1998 ANNUAL REPORT

ESRD CORE INDICATORS PROJECT

OPPORTUNITIES TO IMPROVE CARE FOR ADULT IN-CENTER HEMODIALYSIS and PERITONEAL DIALYSIS PATIENTS

DECEMBER 1998

Department of Health and Human Services
Health Care Financing Administration
Office of Clinical Standards and Quality
Baltimore, Maryland

MEDICARE • MEDICAID
Health Care Financing Administration

Suggested citation for this report is as follows:

Health Care Financing Administration. *1998 Annual Report, End Stage Renal Disease Core Indicators Project*. Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December, 1998.

Note: The clinical data collected for the 1998 ESRD Core Indicators Project were from the time period of October, November, and December, 1997 for the hemodialysis patients and the time period November - December, 1997 and January - April, 1998 for the peritoneal dialysis patients.

Look for this report, as well as other ESRD Core Indicators Project Reports on the Internet at:
www.hcfa.gov/quality/qlty-3c.htm

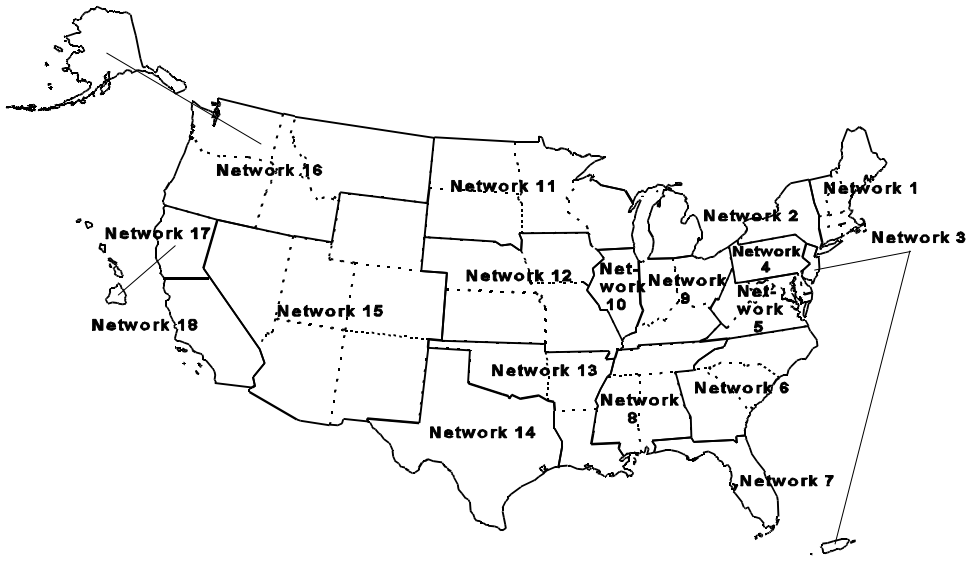
TABLE OF CONTENTS

ACKNOWLEDGMENTS

The Health Care Financing Administration (HCFA) wishes to acknowledge the following groups and persons without whose efforts this report would not have been possible.

- The members of the End Stage Renal Disease (ESRD) Core Indicators Workgroup and the members of the Peritoneal Dialysis Subcommittee (see Appendix 1).
- The eighteen ESRD Network Organizations throughout the United States (see Appendix 2).
- The following HCFA Central Office staff: Ava Marie Chandler, Debbie Grossblatt, George Kattakuzhy, Ron Zeman and Bob Burger.
- Staff at more than 2,500 dialysis facilities in the United States who abstracted the requested information from medical records on more than 8,000 adult in-center hemodialysis and peritoneal dialysis patients.
- The many other individuals in the renal community and HCFA who contributed to this work.

FIGURE 1. Geographic boundaries of the 18 ESRD Network Organizations.



LIST OF TABLES

LIST OF TABLES (continued)

LIST OF FIGURES

LIST OF FIGURES (continued)

LIST OF FIGURES (continued)

LIST OF FIGURES (continued)

1998 ESRD Core Indicators Project

I. BACKGROUND

The Social Security Amendments of 1972 (P.L. 92-603) extended Medicare coverage to individuals with ESRD who require dialysis or a kidney transplant to maintain life. To qualify for Medicare under the renal provision a person must have ESRD and either: be entitled to a monthly insurance benefit under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act); or be fully or currently insured under Social Security; or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. The incidence of treated ESRD in the United States is 180 per million population and continues to rise at a rate of 7.8 percent per year. (1) As of December 31, 1997, there were 230,190 patients receiving dialysis therapy in the United States. (2)

There are 18 ESRD Network Organizations throughout the United States that are under contract to HCFA to perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, HCFA, with input from the renal community, reshaped the ESRD Network program's approach to quality assurance and improvement in order to respond to the need to improve the care of Medicare ESRD patients. (3) This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and HCFA a chance to demonstrate that health care provided to renal Medicare beneficiaries can be measurably improved. The HCQIP is based on the assumption that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management. (4)

The ESRD Core Indicators Project is HCFA's first nationwide population-based study to assess and identify opportunities to improve the care of patients with ESRD. (5) This project has established a consistent clinical database. The elements included in the database represent clinical measures felt to be indicative of key components of care surrounding dialysis. As such, the data points are considered "indicators" for use in triggering improvement activities.

HCFA and the ESRD Networks are committed to improving ESRD patient care and outcomes by providing tools that can be used by the renal community in assessing patient care processes and outcomes and identifying opportunities for improvement. One of these tools includes data feedback reports based on the clinical information obtained from the ESRD Core Indicators Project. We invite the renal community to provide us with ideas and feedback as to ways HCFA and the Networks can best help the community improve patient care.

II. PROJECT METHODS

The purpose of the ESRD Core Indicators Project is to provide comparative data to ESRD care givers to assist them in assessing and improving the care provided to ESRD patients. Data collected in 1994 established baseline estimates for October-December, 1993 for important clinical measures of care for adult, in-center hemodialysis patients in the U.S. (6) In 1995, data were collected on adult, in-center hemodialysis patients for October-December, 1994 and also on peritoneal dialysis patients for November, December, 1994 and January - April, 1995. (7, 8)

The third core indicators data collection effort was conducted in 1996 (9) to determine if patterns in these clinical measures had changed and if opportunities to improve care continued to exist. The fourth data collection effort (10), conducted in 1997, examined data from October-December 1996 for in-center hemodialysis patients and from November- December 1996 and January-April 1997 for peritoneal dialysis patients in order to identify further opportunities to improve care. The fifth data collection effort (which is the subject of this report), conducted in 1998, examined data from October-December 1997 for in-center hemodialysis patients, and from November - December 1997, and January-April 1998 for peritoneal dialysis patients to identify further opportunities to improve care.

The Sample

Annually, each ESRD Network conducts a survey of ESRD facilities to validate the census of ESRD patients in the Network at the end of the calendar year. In March 1998, a listing of adult (aged $ 18 years), in-center hemodialysis and adult peritoneal dialysis patients alive in December 1997 was obtained from each of the 18 ESRD Networks. The listing included the following information about each patient meeting the project criteria: last name, first name, middle initial, date of birth, gender, race, Social Security and/or Health Insurance Claim number, underlying etiology of ESRD, the date that dialysis was initiated, and the provider number of the facility where the patient was dialyzing.

From this universe of patients we selected a random sample of in-center hemodialysis patients, stratified by Networks and a national random sample of peritoneal dialysis patients. The hemodialysis patient sample size was determined by our desire to be 95% confident that Network-specific estimates for selected clinical measures be accurate within +/- 5%. We over sampled by 15% to compensate for an anticipated non-response rate. The final sample consisted of 7,658 in-center hemodialysis patients and 1,499 peritoneal dialysis patients.

Data Collection

A one page hemodialysis and a two page peritoneal dialysis data collection form were used (Appendices 3 & 4); the use of these forms was authorized through the National Institutes of Health clinical exemption process. Descriptive information on each selected patient was printed onto gummed labels which were placed on the appropriate data collection forms before the forms were sent to individual ESRD facilities to be completed. If demographic (e.g. name, date of birth, or race) or clinical (e.g. diagnosis of ESRD or date that initial dialysis occurred) information was incorrect, facility staff were asked to correct the information. Staff at ESRD facilities were also asked to abstract ethnicity and clinical information from each selected patient's medical record.

In May, 1998, the data collection forms for patients in the sample were distributed to ESRD facilities. Completed forms were returned to the appropriate Network where data were reviewed for acceptability and manually entered into an Epi Info, v.6.04a file. (11) By August 10, 1998, each Network had sent a copy of the resulting Epi Info, v 6.04a file to HCFA Central Office in Baltimore where the data were aggregated for the initial analysis.

Clinical information in the selected patients' medical records was abstracted for each patient in the hemodialysis sample who was receiving in-center hemodialysis during the months of October, November, and December 1997 and for each patient in the peritoneal dialysis sample who was receiving peritoneal dialysis during the two-month periods of November-December 1997, January-February 1998, and March-April 1998. Please refer to the data collection forms contained in Appendices 3 & 4 for the clinical information that was abstracted on each patient (in-center hemodialysis and peritoneal dialysis) included in the study.

Core Indicators

Using the clinical information abstracted by facility staff, we were able to describe the prevalence of several conditions of care which we call core indicators. The core indicators used in this project were identified by a workgroup (see Appendix 1) composed of representatives from the renal community, the ESRD Networks and HCFA. The core indicators identified were:

1. Adequacy of Dialysis: as measured by the urea reduction ratio (URR) and/or Kt/V for in-center hemodialysis patients; and weekly Kt/V and/or weekly creatinine clearance for peritoneal dialysis patients.

Based on the Renal Physicians Association clinical practice guideline, an NIH Consensus Conference statement, and the National Kidney Foundation's (NKF) Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines for Hemodialysis Adequacy, the mean URR of 65% or more was defined as adequate hemodialysis. (1,12,13) The URR measurement of 65% is approximately equivalent to the Kt/V measurement of 1.2. (12,13) [URR = (pre-dialysis BUN minus post-dialysis BUN)/pre-dialysis BUN].

Based on the DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy, adequate dialysis for peritoneal dialysis patients is defined as a mean Kt/V urea of 2.1 for cycler patients with daytime dwell, 2.2 for cycler patients without daytime dwell, and 2.0 for patients on Continuous Ambulatory Peritoneal Dialysis (CAPD). (14)

Findings from this project allow us to describe the mean URR and Kt/V values for hemodialysis patients in each Network area as well as the percent of hemodialysis patients in the U.S. with a delivered URR $ 65%, and a delivered Kt/V $ 1.2.

2. Anemia Management: as measured by the hematocrit and hemoglobin values for both in-center hemodialysis and peritoneal dialysis patients. Findings from this project allow us to describe the mean hematocrit and hemoglobin values for hemodialysis patients in each Network area and nationally for peritoneal dialysis patients. We are also able to describe the percent of patients with mean hematocrit values > 30%, the percent of patients receiving Epoetin with mean hematocrits between 33% - 36%, the target range recommended by the DOQI Clinical Practice Guidelines for the Treatment of Anemia, the percent of patients with mean hematocrit $ 33%, and the percent of patients with mean hematocrit <28% (defined as severe anemia for this Report). (15)

All monthly recorded data were used in determining the percent of patients receiving Epoetin, and the average weekly Epoetin dose stratified by hematocrit levels.

3. Serum Albumin: Serum albumin was chosen as an indicator for assessing mortality risk for adult in-center hemodialysis and peritoneal dialysis patients. Serum albumin values are described separately for those patients whose blood was tested by the bromcresol green (BCG) method or by the bromcresol purple (BCP) method. These two commonly used methods for determining serum albumin concentrations have been reported to yield systematically different results; the BCG method yielding higher serum albumin concentrations than the BCP method. (16)

Mean serum albumin values < 3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin values. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin values. Findings from this project allow us to describe the mean serum albumin value for hemodialysis patients in each Network area and nationally for peritoneal dialysis patients.

4. Blood Pressure Levels: for the peritoneal dialysis patient sample only, systolic and diastolic blood pressure values were abstracted for each two-month period to assess the control of blood pressure. Patients were categorized by the definitions used in the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC6). (17)

III. INITIAL ANALYSIS

Hemodialysis:

Initial analysis focused on three clinical measures: paired pre- and post-dialysis BUN values (used to calculate URR values); paired pre- and post-dialysis BUN values with patient height and weight and dialysis session length (used to calculate Kt/V values); hematocrit values; and serum albumin values. Inclusion of a case in the analysis required that data be available for at least one of the months in the three month project period, with three clinical measures being present. We were able to include for analysis 7,092 of the 7,658 patients from the sample (response rate=93%) (TABLE 1).

Characteristics regarding the gender, race, age, and diagnosis of ESRD for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall U.S. hemodialysis population. (18) Data regarding hemoglobin values, Epoetin use, ferritin concentrations, transferrin saturation levels, iron use, Kt/V, KUf (a measure of dialyzer clearance), and actual time on dialysis were also analyzed. The initial analysis utilized Epi Info and Statistical Package for the Social Sciences (SPSS) software. (11,19)

For this report each patient's mean monthly value for the three month project period was determined from the available data for the following items: URR, Kt/V, time on dialysis, KUf, hematocrit, hemoglobin, and serum albumin. Because we had data from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Network areas), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

Peritoneal Dialysis:

Initial analysis focused on the adequacy of dialysis measures, anemia management measures, serum albumin values, and blood pressure values. Inclusion of a case for analysis required that the patient received peritoneal dialysis at least one of the two-month time periods from November 1997 - April 1998. 1,381 patients of the 1,499 patients from the sample were included for analysis (92% response rate) (TABLE 3). Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient's mean value for the six month study period was determined from available data for the following items: weekly Kt/V urea, weekly creatinine clearance, hematocrit, hemoglobin, serum albumin, systolic and diastolic blood pressure values, Epoetin dosing, ferritin concentrations, and transferrin saturation levels. Iron use for the patients in this sample was analyzed. The data are from a random sample, not stratified by Network, thus, only national aggregate data are reported. No Network specific analyses were conducted.

Report Format

This report describes the core indicators findings for both the hemodialysis patient sample and the peritoneal dialysis patient sample in separate sections, VI and VII respectively, for the following study period: October, November, December 1997 for the hemodialysis patients and November, December 1997 and January-April 1998 for the peritoneal dialysis patients.

The national results are presented separately in tables by gender, race, age groups (18-44, 45-64, and 65+ years of age), and diagnosis of ESRD. The diagnoses are categorized as diabetes mellitus (DM), hypertension (HTN), glomerulonephritis (GN), and other/unknown. In some instances clinical characteristics for patients in each Network area are also shown. Selected results are highlighted in figures.

In addition, key findings from the 1998 Core Indicators study (describing patterns of clinical measures from October-December 1997 for hemodialysis patients and November 1997-April 1998 for peritoneal dialysis patients) are compared to key findings from previous study periods.

TABLE 1: Number of adult (aged $18 years), in-center hemodialysis patients in each Network in Dec 1997, sample size and response rate for the 1998 ESRD Core Indicators Project.

Network	# HD Patients Dec 1997	Sample Size	# Acceptable Forms^	Response Rate %
1	7,514	420	385	91.7
2	15,625	432	383	88.6
3	9,052	425	406	95.5
4	9,997	426	388	91.1
5	13,019	429	411	95.8
6	18,042	433	391	90.3
7	11,909	428	404	94.4
8	12,092	426	397	93.2
9	11,309	428	399	93.2
10	7,986	423	389	92.0
11	12,100	428	400	93.4
12	7,137	420	351	83.6
13	8,796	424	405	95.5
14	16,151	432	407	94.2
15	7,839	421	407	96.7
16	4,586	408	364	89.2
17	8,980	424	396	93.4
18	14,595	431	409	94.9
Total	196,729	7,658	7,092	92.6

^ A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 1997, for the following items: 1) hematocrit; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 96% of patients for hematocrit, and for serum albumin by either BCG or BCP method. Monthly hematocrit values were available for 90% of patients. At least one monthly paired pre-and post-dialysis BUN value was available for 100% of patients, and two or more were available for 88%. Monthly paired pre- and post-dialysis BUN values were available for 74% of patients.

TABLE 2: Characteristics of adult (aged $18 years), in-center hemodialysis patients in the 1998 ESRD Core Indicators Project compared to those of all in-center hemodialysis patients in the U.S. in 1996.

Patient Characteristic	1998 Core Indicators Sample for Analysis		All U.S. in 1996*	
	# ^	%	# in 1000s	%
TOTAL	7092	100	175.4	100
GENDER				
Men	3753	53	91.3	52
Women	3329	47	84.1	48
RACE/ETHNICITY				
American Indian/ Alaska Native	135	2	3.0	2
Asian/Pacific Islander	294	4	6.1	3
African-American	2593	37	69.3	40
Caucasian	3636	52	93.5	53
Other/Unknown	403	6	3.6	2
Hispanic	844	12		
AGE GROUP - years				
18-44	1204	17	30.4**	17
45-64	2574	37	64.6	37
65+	3244	46	79.5	45
DIAGNOSIS				
Diabetes mellitus	2764	39	65.5	37
Hypertension	1909	27	51.7	29
Glomerulonephritis	905	13	22.7	13
Other/Unknown	1471	21	35.5	20

*USRDS: 1998 Annual Data Report, Bethesda, MD, National Institutes of Health, 1998

** For ages 20-44 years

^ when subgroup totals do not equal 7092, due to missing data

Note: Percents may not add up to 100% due to rounding

TABLE 3: Number of adult (aged $18 years) peritoneal dialysis patients in each Network's sample and response rate for the 1998 ESRD Core Indicators Project.

Network	Sample Size	# Acceptable Forms^	Response Rate %
1	67	62	92.5
2	97	87	89.7
3	76	74	97.4
4	75	60	80.0
5	91	88	96.7
6	141	124	87.9
7	76	72	94.7
8	74	65	87.8
9	126	115	91.3
10	50	47	94.0
11	103	101	98.0
12	92	80	86.9
13	61	60	98.4
14	88	79	89.8
15	59	56	94.9
16	47	46	97.9
17	76	74	97.4
18	100	91	91.0
Total	1499	1381	92.1

^ A form was considered acceptable if the patient was receiving peritoneal dialysis at least one of the two-month periods during the six month study period and had met the selection criteria for inclusion in the study.

Two or more values over the six month study period for these clinical measures were available for 94% of patients for hematocrit and 93% of patients for serum albumin levels either by BCG or BCP method, and 91% of patients for paired systolic and diastolic blood pressure values. Approximately 81% of patients had adequacy of dialysis assessed at least once during the six month study period.

TABLE 4: Characteristics of adult (aged $18 years), peritoneal dialysis patients in the 1998 ESRD Core Indicators Project.

Patient Characteristic	1998 Core Indicators Sample for Analysis # ^	%
TOTAL	1381	100
GENDER		
Men	698	51
Women	679	49
RACE/ETHNICITY		
American Indian/ Alaska Native	15	1
Asian/Pacific Islander	55	4
African-American	389	28
Caucasian	838	61
Other/Unknown	76	6
Hispanic	136	10
AGE GROUP (years)		
18-44	384	28
45-64	589	43
65+	403	29
DIAGNOSIS		
Diabetes mellitus	496	36
Hypertension	286	21
Glomerulonephritis	232	17
Other/Unknown	351	26

^ when subgroup totals do not equal 1381, due to missing data

Note: Percents may not add up to 100% due to rounding

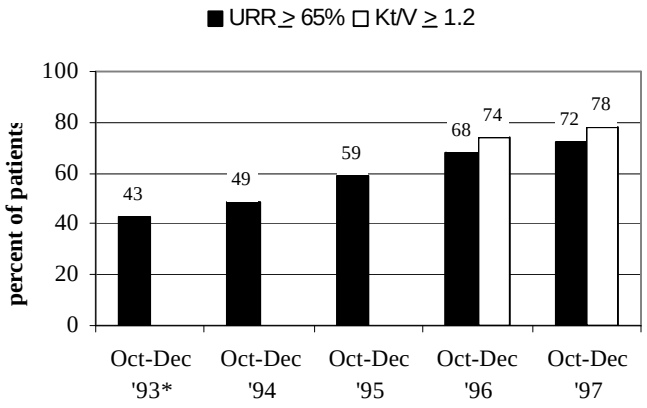
IV. IMPROVEMENTS AND OPPORTUNITIES TO IMPROVE CARE

By describing the prevalence of important clinical characteristics of adult, in-center hemodialysis patients in the U.S. in October-December 1993, October-December 1994, October-December 1995, October-December 1996, and again in October-December 1997 this project has documented important improvements in and continuing opportunities to improve care for these patients.

Striking improvement in the adequacy of dialysis for in-center hemodialysis patients occurred. However, important opportunities to improve this care further remain.

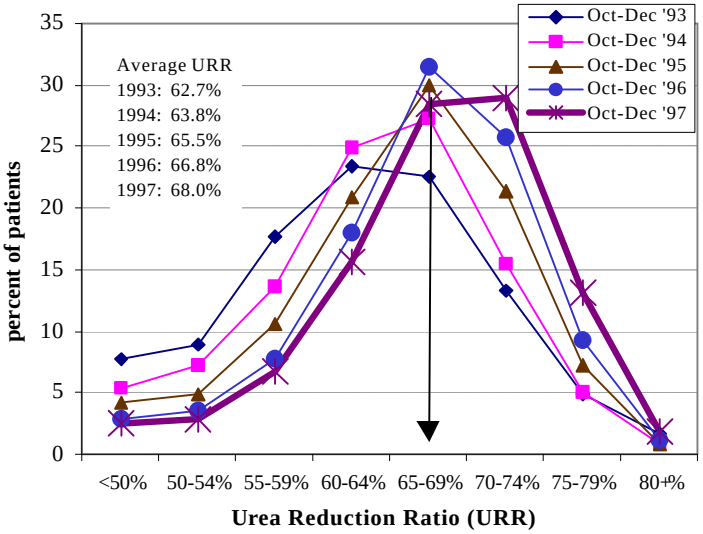
In the last quarter of 1997, 72% of the sampled adult, in-center hemodialysis patients in the U.S. received dialysis which resulted in a URR $ 65%. The percent of patients receiving dialysis at this URR level increased significantly from 68% to 72% from late 1996 to late 1997 (FIGURE 2). This represents a significant improvement in care, with approximately 57,000 more hemodialysis patients in the U.S. receiving dialysis with URR $ 65% in late 1997 than would have been receiving dialysis at this level in late 1993 (FIGURE 3a). At the same time, approximately 28% of the patients were receiving dialysis with URR< 65%. A similar pattern was seen for the distribution of Kt/V values from late 1996 to late 1997 (FIGURE 3b).

FIGURE 2: Percent of adult (aged $ 18 years) in-center hemodialysis patients with mean URR $ 65% in Oct- Dec 1997 compared to Oct-Dec 1993*, 1994, 1995, and 1996, and percent with mean Kt/V$ 1.2, Oct-Dec 1997 compared to Oct-Dec 1996. 1998 ESRD Core Indicators Project.



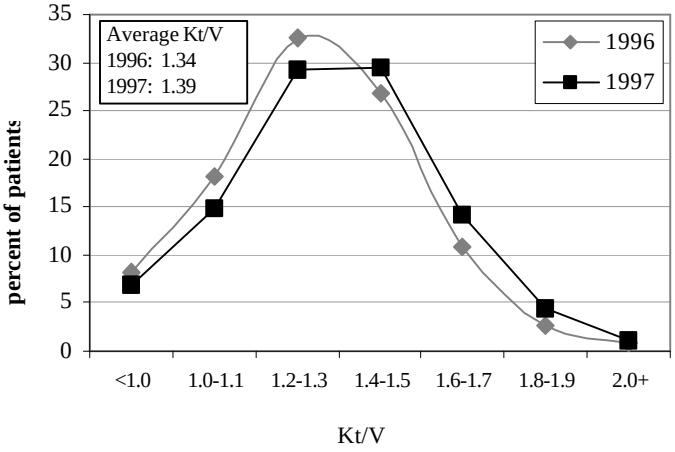
* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Network areas participated in subsequent years.

FIGURE 3a: Distribution of URR values for adult (aged $18 years), in-center hemodialysis patients October -December 1997 compared to October-December 1993*, 1994, 1995, and 1996. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Network areas participated in subsequent years.

FIGURE 3b: Distribution of Kt/V values for adult (aged $18 years), in-center hemodialysis patients, October-December 1997 compared to October-December 1996. 1998 ESRD Core Indicators Project.



Another important improvement occurred in hematocrit levels of the sampled in-center hemodialysis patients. In late 1993, 46% of adult in-center hemodialysis patients in the 16 participating Networks had a mean hematocrit > 30%, by late 1997 this percent had increased to 79% (FIGURES 4,5) in all 18 Networks. One goal of the National Anemia Cooperative Project is to increase the percent of patients with hematocrit > 30%. (20)

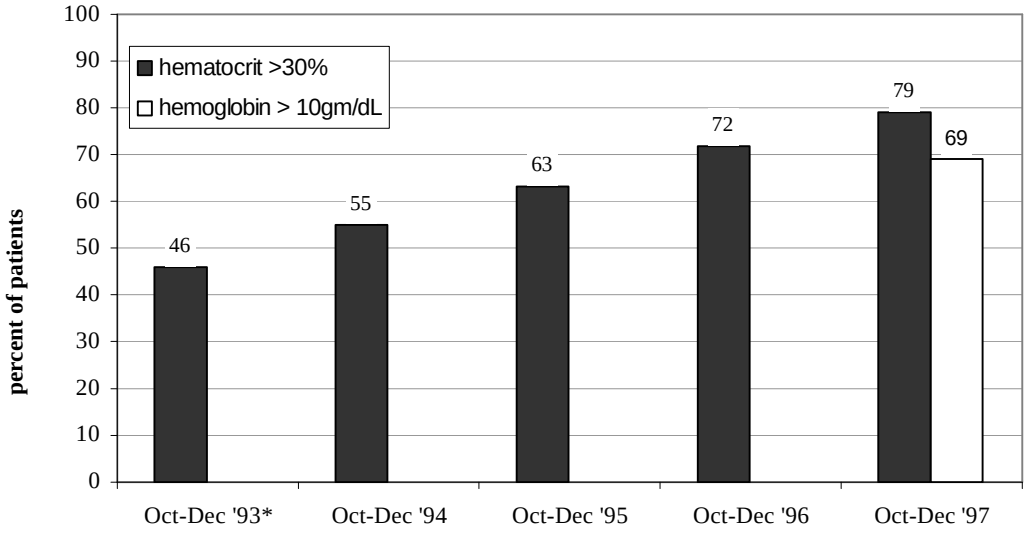
A similar improvement in hematocrit levels was also seen in the sampled peritoneal dialysis patients. The average hematocrit level for these patients in the 1995 study period was 32.5%, 33.1% in the 1996 study period and 33.8% in the 1997 and 1998 study periods (FIGURE 6). The percentage of sampled peritoneal dialysis patients with a mean hematocrit level > 30% was 64% in the 1995 study period, 70% in the 1996 study period, 76% in the 1997 study period, and 78% in the 1998 study period.

Improvement in the adequacy of dialysis occurred for CAPD patients. The mean weekly Kt/V urea increased from 2.12 to 2.20 and the mean weekly creatinine clearance increased from 65.8 to 67.8 L/week/1.73 m^2 from study year 1997 to study year 1998 (FIGURES 7a, 7b).

The purpose of this report is to provide you with an initial look at the Network and national pictures of the clinical measures that were collected for the ESRD Core Indicators Project. The project did not attempt to develop facility-specific profiles of care.

As you review this information, ask yourself: What percentage of adult patients at your facility are receiving adequate dialysis (URR $ 65% or Kt/V$1.2 for in-center hemodialysis patients)? What percentage of your patients have an average hematocrit > 30%? How do these indicators of care for your patients compare to the indicators described in this report? We want this report to stimulate you to answer questions such as these and, where indicated, to develop ways to improve care to your patients.

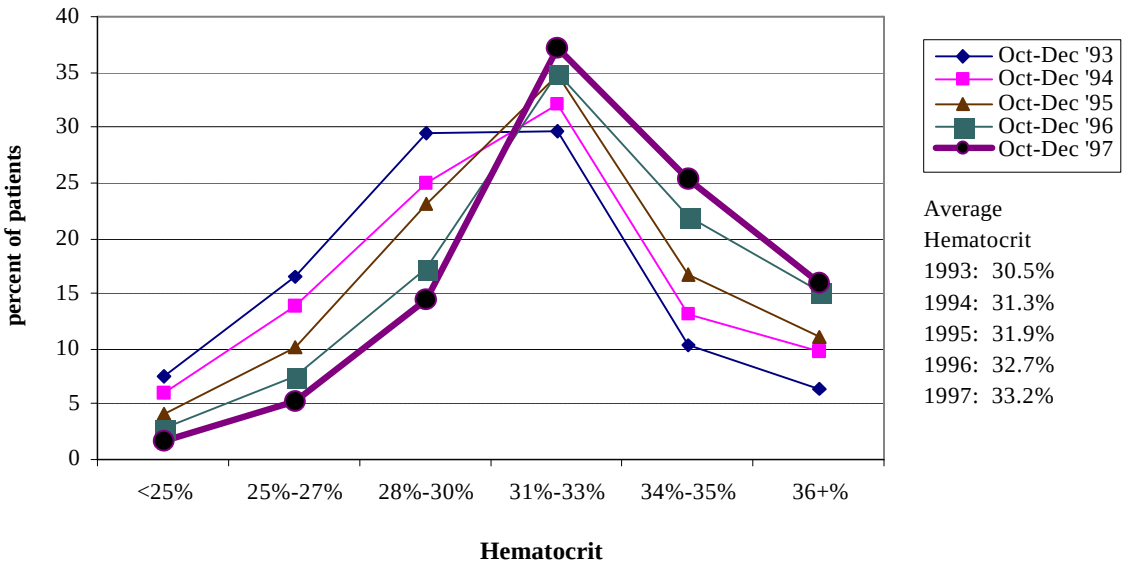
FIGURE 4: Percent of adult (aged $18 years), in-center hemodialysis patients with mean hematocrit > 30% in October-December 1997 compared to October-December 1993*, 1994, 1995, and 1996, and percent of patients with hemoglobin >10 gm/dL^, October-December 1997. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Network areas participated in subsequent years.

^Although many approximate the hematocrit by multiplying the hemoglobin by three (or dividing the hematocrit by three to approximate the hemoglobin), this formula is not a valid method to obtain the hematocrit or hemoglobin value because the relationship between hematocrit and hemoglobin differs significantly depending upon the instrumentation used to measure them (21).

FIGURE 5: Distribution of hematocrit values for adult (aged $ 18 years), in-center hemodialysis patients, October-December 1997 compared to October-December 1993*, 1994, 1995, and 1996. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Network areas participated in subsequent years.

FIGURE 6: Distribution of hematocrit values for adult (aged $ 18 years), peritoneal dialysis patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

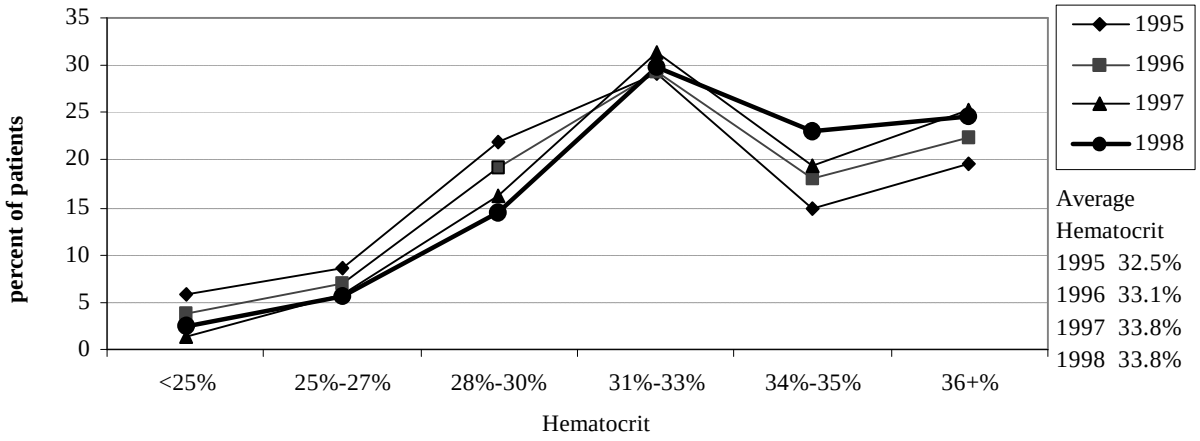


FIGURE 7a: Distribution of weekly Kt/V urea values for adult (aged $18 years) CAPD patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

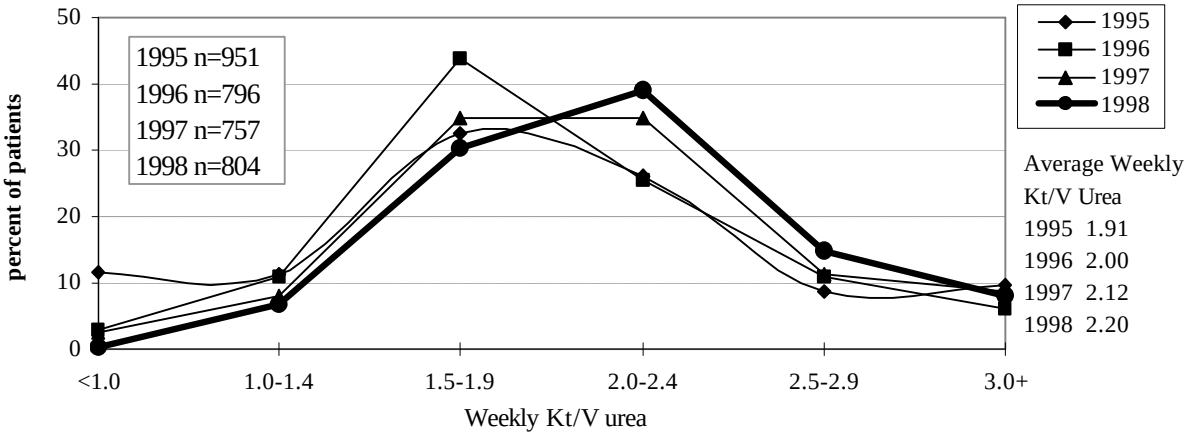
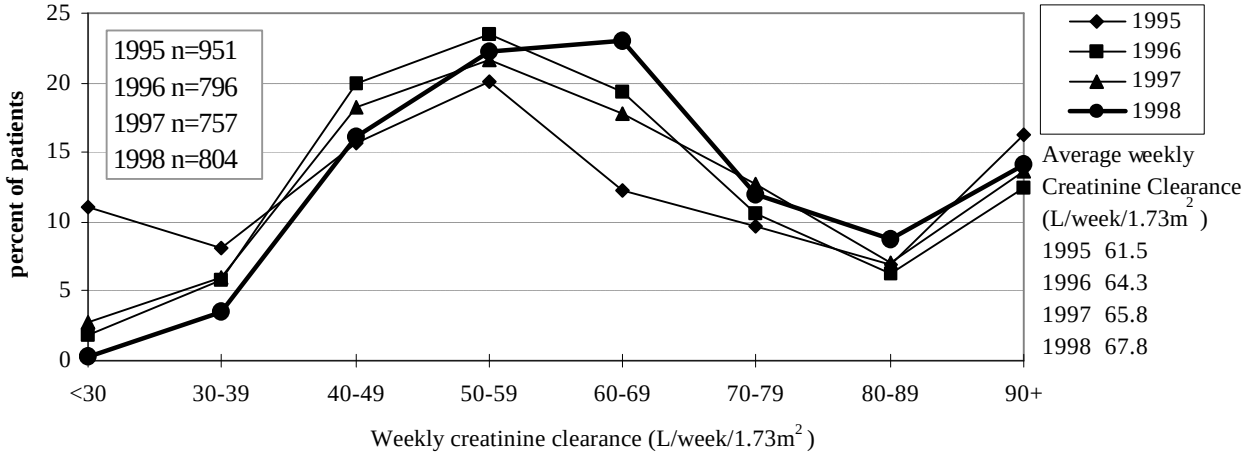


FIGURE 7b: Distribution of weekly creatinine clearance values (L/week/1.73m^2) for adult (aged $ 18 years) CAPD patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97.
1998 ESRD Core Indicators Project.



V. NEXT STEPS

Copies of the initial results of the 1998 ESRD Core Indicators Project will be distributed to all dialysis facilities for the purpose of stimulating facility efforts to improve care. Your Network staff and Medical Review Board will be available to assist you in identifying and developing improvement efforts.

As mentioned previously, while significant improvements have occurred, the opportunity to improve care for adult, in-center hemodialysis patients and peritoneal dialysis patients in the U.S. in the area of adequacy of dialysis continues to be striking. Every ESRD facility should be familiar with the clinical practice guidelines on adequacy of dialysis developed by the Renal Physicians Association (12) and the NKF's DOQI. (13,14)

Factors that contribute to the inadequate delivery of dialysis are discussed in these documents. Efforts to improve the adequacy of dialysis should be attentive to these factors.

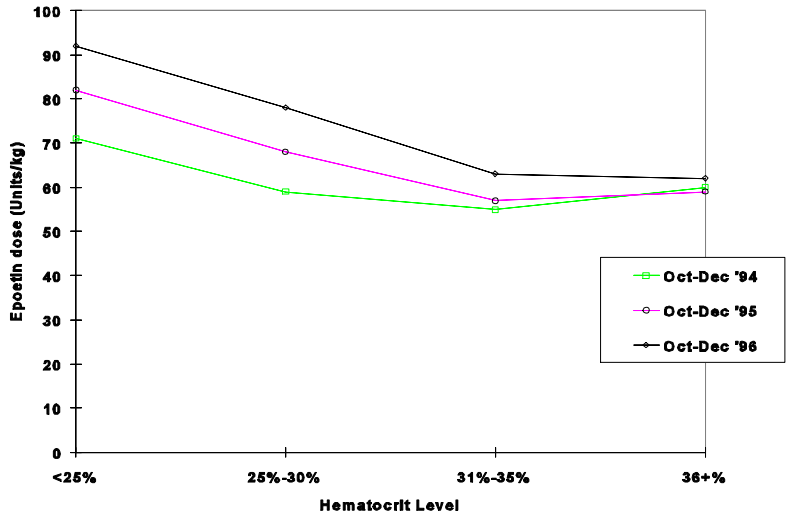
In subsequent months, your ESRD Network will distribute to you additional data feedback reports. You may also find these reports on the Internet at www.hcfa.gov/quality/qlty-3c.htm. Please take the time to review these reports as you receive them and provide us with feedback as to the usefulness of the reports and ways you would like to see the clinical data displayed.

In the future, the ESRD Networks in collaboration with ESRD facilities will continue to assess the prevalence of the ESRD Core Indicators in adult, in-center hemodialysis and peritoneal dialysis patients in the U.S. The purpose of this effort will be to assess improvement in care to these patients and encourage further improvements. The ultimate goal for this project is to improve care for these patients.

Erratum to the ESRD Core Indicators 1997 Annual Report

Figure 26 was inadvertently omitted from the first printing of the 1997 ESRD Core Indicators Annual Report. The following figure should have appeared on page 37 of that Report.

FIGURE 26: Mean Epoetin dose (units/kg) for adult (aged $ 18 years), in-center hemodialysis patients, by hematocrit category, October-December 1996 compared to October-December 1994, and 1995. 1997 ESRD Core Indicators Project.



VI. HEMODIALYSIS PATIENTS

A. SYNOPSIS

- Purpose of Project: The ultimate purpose of the ESRD Core Indicators Project is to assist providers of ESRD services to improve care provided to ESRD patients. The immediate purposes of the 1998 project were:

  To compare the prevalence of important clinical characteristics of adult (aged ≥ 18 years), in-center hemodialysis patients in the U.S. in Oct-Dec 1997 to the prevalence of those characteristics in Oct-Dec 1993, Oct-Dec 1994, Oct-Dec 1995, and Oct-Dec 1996; AND, To identify opportunities to improve care for those patients.

- Method Used: A random sample of adult, in-center hemodialysis patients who were alive on December 31, 1997 was selected (sample size 7658).

ESRD facilities, with assistance from ESRD Networks, submitted to HCFA clinical information about these patients for the time period October, November, December, 1997.

- Initial Findings: Data were submitted for 7092 (93%) of the patients in the sample. Highlights from the initial findings include:

IMPROVEMENT OCCURRED

- 72% of the sampled patients were receiving dialysis with urea reduction ratio (URR) ≥ 65%; there was a 4 percentage point increase in patients receiving dialysis with URR ≥ 65% from late 1996 to late 1997 (FIGURE 2).

- 69% of African-Americans and 73% of Caucasians were receiving dialysis with URR ≥ 65%, in Oct-Dec 1997; this was a 6 percentage point increase for African-American patients and a 3 percentage point increase for Caucasian patients from late 1996 to 1997 (FIGURE 12).

- 79% of patients had a mean hematocrit > 30% in the last quarter of 1997 compared to 72% of the patients in the last quarter of 1996, a 7 percentage point increase from late 1996 to late 1997 (FIGURE 4).

- 9% of African-Americans and 6% of Caucasians were severely anemic (severe anemia for this report is defined as hematocrit < 28%) in Oct-Dec 1997 compared to 12% and 9% respectively, in Oct-Dec 1996.

- There exists variation among Networks for percentages of patients receiving hemodialysis with a delivered URR ≥ 65% (range from 65% - 78%) (TABLE 6a) and for percentages of patients with hematocrit levels > 30% (range from 72% - 85%) (FIGURE 19a).

LITTLE OR NO CHANGE

- Approximately 1 in 5 patients had serum albumin levels < 3.5 gm/dL (BCG method) or < 3.2 gm/dL (BCP method) , reflecting little change from previous study years.

- Next Steps: Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to document further improved care for ESRD patients in 1999 and 2000.

B. ADEQUACY OF DIALYSIS

This section and sections C and D will consist of two parts: (1) Core Indicators results from 18 ESRD Network areas for October-December 1997; and (2) a comparison of Core Indicators results for October-December 1997 and previous study period(s).

1. October-December 1997

The mean URR for the national sample of adult, in-center hemodialysis patients in the last quarter of 1997 was 68.0%. The distribution of URR values for these patients is shown in Figure 8a. The mean Kt/V was 1.39; the distribution of Kt/V values is shown in Figure 8b. The mean URR and Kt/V values, and the percent of patients with URR $\geq$ 65%, Kt/V $\geq$ 1.2 , and Kt/V $\geq$ 1.25 for gender, race, age, and diagnosis are shown in Table 5.

The Renal Physicians Association, an NIH Consensus Development Conference Panel, and the NKF DOQI Clinical Practice Guidelines for Hemodialysis Adequacy have recommended that adequate hemodialysis should result in a Kt/V $\geq$ 1.2, approximately equivalent to URR $\geq$ 65%. (1,12,13) The percent of patients who received adequate hemodialysis by this definition in the last quarter of 1997 was 72% (TABLE 5). The percent of patients receiving hemodialysis with a URR $\geq$ 65% was higher for women than for men, higher for Caucasians than for African-Americans, higher for patients $\geq$ 65 years of age than for those 18-44 and 45-64 years of age, and for non-diabetics compared to diabetics (TABLE 5, FIGURE 9).

The percent of patients who received adequate hemodialysis varied substantially from one geographic region to another. Table 6a shows the percent of patients who received hemodialysis with a URR $\geq$ 65% by race and gender in each Network area; the percent ranged from 65% to 78% (FIGURES 10a, 11a). Similarly, Table 6b shows the percent of patients by Network, race, and gender with a delivered Kt/V $\geq$ 1.2; the percent ranged from 71% to 84% (FIGURES 10b, 11b).

The mean time spent on dialysis per dialysis session was 210 minutes. The mean time spent on dialysis was somewhat longer for men than women (217 minutes vs. 203 minutes), and African-Americans than Caucasians (215 minutes vs. 208 minutes). The mean time spent on dialysis did not differ substantially for patients by either URR or Kt/V category.

FIGURE 8a: Distribution of mean URR values for adult (aged $\geq$18 years), in-center hemodialysis patients, October-December 1997. 1998 ESRD Core Indicators Project.

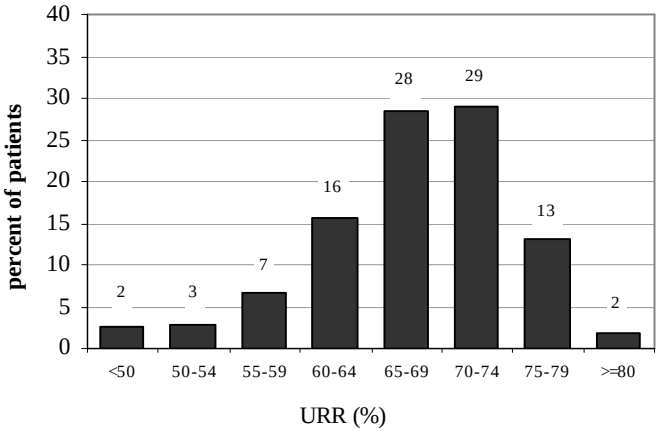
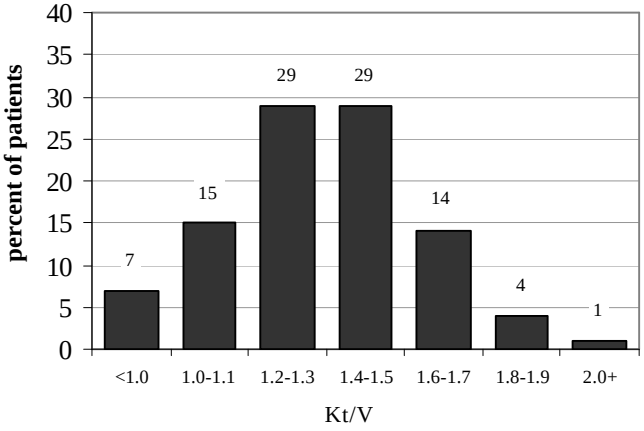


FIGURE 8b: Distribution of mean Kt/V values for adult (aged $\geq$18 years), in-center hemodialysis patients, October-December 1997. 1998 ESRD Core Indicators Project.



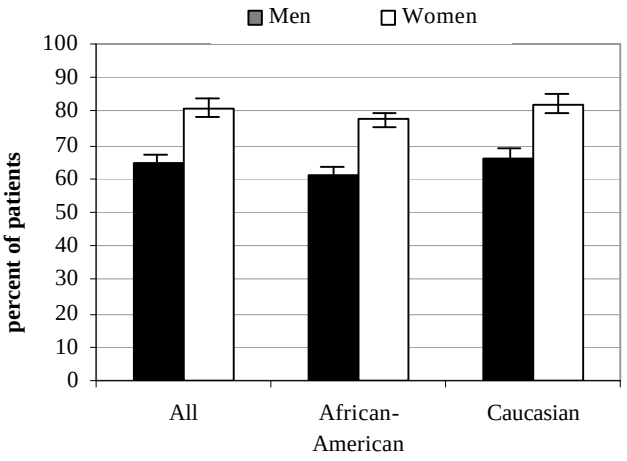
Note Regarding Race:
In this report several tables describe important clinical characteristics of adult in-center hemodialysis and peritoneal dialysis patients for the following race groups: American Indian/ Alaska Native, Asian/Pacific Islander, African-American, Caucasian, and other/unknown. In the figures where these clinical characteristics are compared by race group, however, the comparisons are limited to Caucasian vs. African-American. The reason for this is sample size. Because of small sample size (Table 2) the 95% confidence intervals (see note regarding statistics p. 22) for estimates for Asian/Pacific Islander, American Indian/Alaska Native, or other/unknown race groups are very broad. On the other hand, the sample size for Caucasian and African-American patients was large enough to provide very stable estimates, i.e., the 95% confidence intervals are narrow.

TABLE 5: Mean URR, mean Kt/V, and percent of adult (aged ≥ 18 years), in-center hemodialysis patients with URR ≥ 65%, Kt/V ≥ 1.2, and Kt/V ≥ 1.25, October-December 1997, by patient characteristics.
1998 ESRD Core Indicators Project.

Patient Characteristics	Mean URR (%)	URR ≥ 65%	Mean Kt/V	Kt/V ≥ 1.2	Kt/V ≥ 1.25
TOTAL	68	72	1.39	78	72
GENDER					
Men	66	65	1.33	73	66
Women	70	81	1.45	85	80
RACE					
American Indian/ Alaska Native	69	77	1.45	81	77
Asian/Pacific Islander	71	88	1.51	90	88
African-American	67	69	1.36	77	70
Caucasian	68	73	1.40	78	72
Other/ Unknown	68	73	1.41	77	73
AGE GROUP -yrs					
18-44	67	66	1.37	74	68
45-64	67	69	1.36	76	69
65+	69	78	1.41	81	76
DIAGNOSIS					
Diabetes mellitus	68	70	1.38	77	71
Hypertension	68	75	1.40	80	74
Glomerulonephritis	68	72	1.38	78	72
Other/Unknown	68	73	1.40	78	72

Note: Because convective clearance is not accounted for by the URR, the mathematical relationship between URR and Kt/V will vary. Caution is urged in extrapolating frequency distribution curves of dialysis adequacy using URR versus Kt/V. A delivered URR 65% does not necessarily correlate with a delivered Kt/V 1.2.

FIGURE 9: Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean URR ≥ 65%, October-December 1997, by race and gender.
1998 ESRD Core Indicators Project.



Note Regarding Statistics:
Readers may be interested to know if some of the patterns of clinical characteristics in this report show statistically significant differences, e.g., comparisons among age groups, racial groups, or geographic areas. To assist readers we have included 95% confidence interval (CI) brackets (I) on selected bar charts. If the upper limit of one group's bracket does not overlap with the lower limit of another group's bracket, then the difference between the two groups is statistically significant. In Figure 9, for example, the percent of all women receiving adequate dialysis is statistically significantly higher than the percent of all men receiving adequate dialysis.

TABLE 6a: Percent of adult (aged $18 years), in-center hemodialysis patients receiving dialysis with a mean URR $ 65%, October-December 1997, by patient characteristics and Network. 1998 ESRD Core Indicators Project.

PATIENT CHARACTERISTIC	NETWORK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ALL	77	70	72	76	65	75	72	71	72	66	69	76	68	78	75	74	71	73
RACE																		
African-American	68	66	67	64	64	75	73	72	70	62	71	79	66	72	63	72	59	73
Caucasian	78	74	77	82	65	76	72	71	72	72	67	75	68	75	74	74	61	74
MEN																		
African-American	66	58	61	58	59	67	59	64	57	53	64	67	51	72	57	61	55	62
Caucasian	72	69	70	75	52	66	62	66	66	66	60	68	61	67	69	67	52	68
WOMEN																		
African-American	71	75	77	72	70	80	87	79	84	73	80	94	82	73	69	81	63	84
Caucasian	88	79	89	92	84	86	87	80	82	82	74	84	78	84	80	82	74	80

Note: A delivered URR 65% does not necessarily correlate with a delivered Kt/V 1.2.

TABLE 6b: Percent of adult (aged $18 years), in-center hemodialysis patients receiving dialysis with a mean Kt/V $ 1.2, October-December 1997, by patient characteristics and Network. 1998 ESRD Core Indicators Project.

PATIENT CHARACTERISTIC	NETWORK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ALL	83	77	75	83	71	80	79	80	79	73	75	79	75	84	81	79	76	78
RACE																		
African-American	73	74	71	79	68	80	80	82	81	72	78	82	75	81	81	74	64	77
Caucasian	84	80	78	85	74	82	79	77	77	77	72	78	75	82	80	79	71	78
MEN																		
African-American	73	68	65	76	64	74	71	75	74	69	73	71	61	81	79	61	62	65
Caucasian	81	77	75	80	65	76	73	70	72	72	68	71	71	77	78	74	60	72
WOMEN																		
African-American	74	82	81	82	73	84	90	88	89	76	84	97	88	81	83	86	66	90
Caucasian	88	83	85	91	85	88	90	88	85	83	75	86	82	88	83	84	87	84

Note: A delivered URR 65% does not necessarily correlate with a delivered Kt/V 1.2.

FIGURE 10a. Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR $ 65%, October - December 1997, by Network. 1998 ESRD Core Indicators Project.

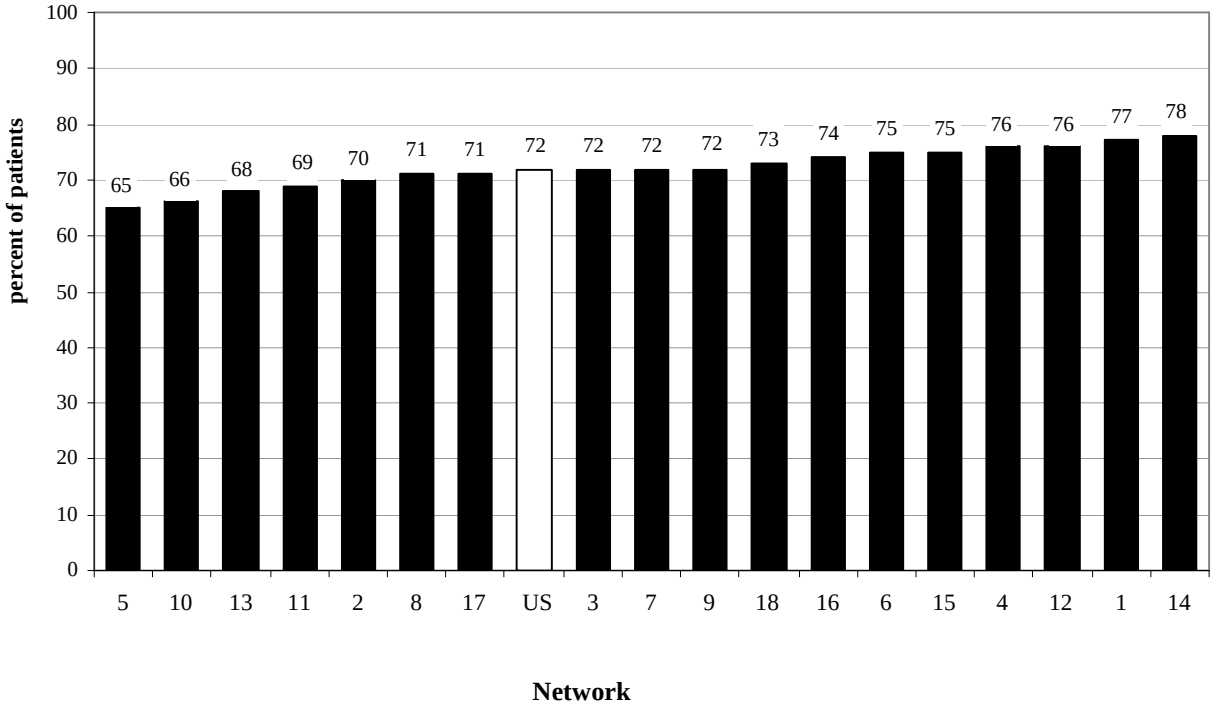


FIGURE 10b. Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving dialysis with a mean Kt/V $ 1.2, October - December 1997, by Network. 1998 ESRD Core Indicators Project.

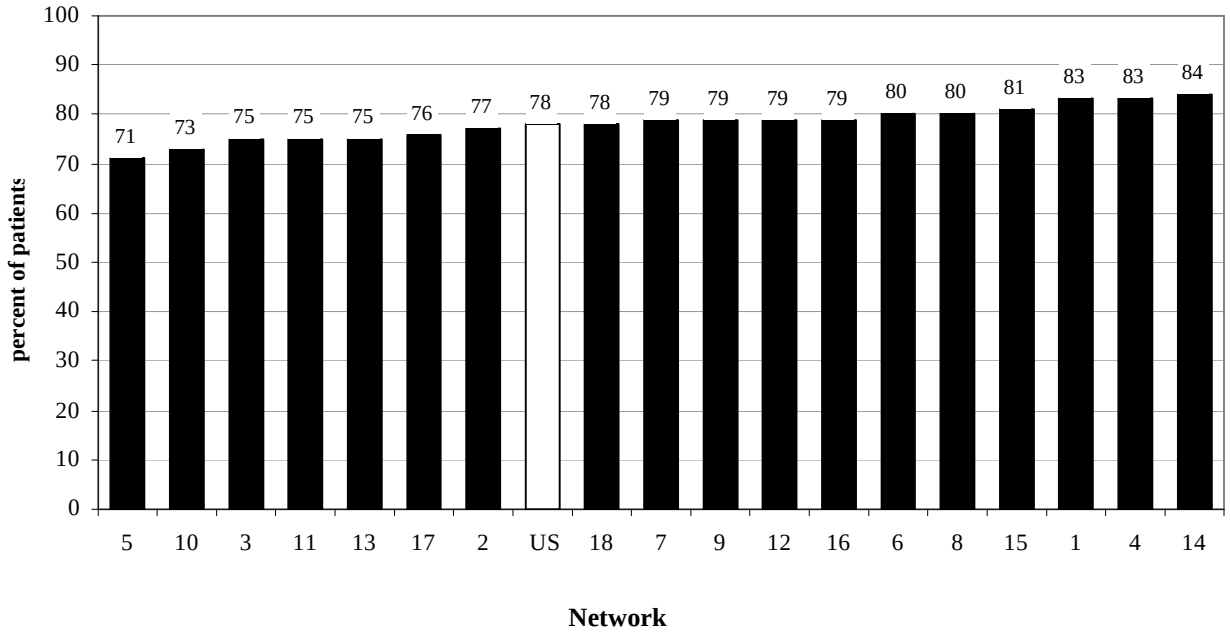


FIGURE 11a: Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR $ 65%, October-December, 1997, by Network. 1998 ESRD Core Indicators Project.

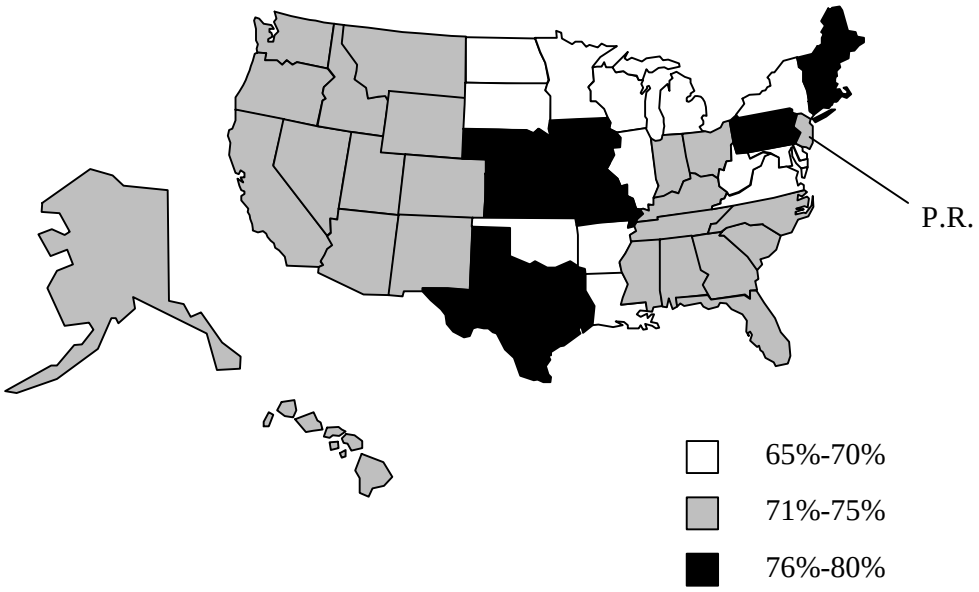
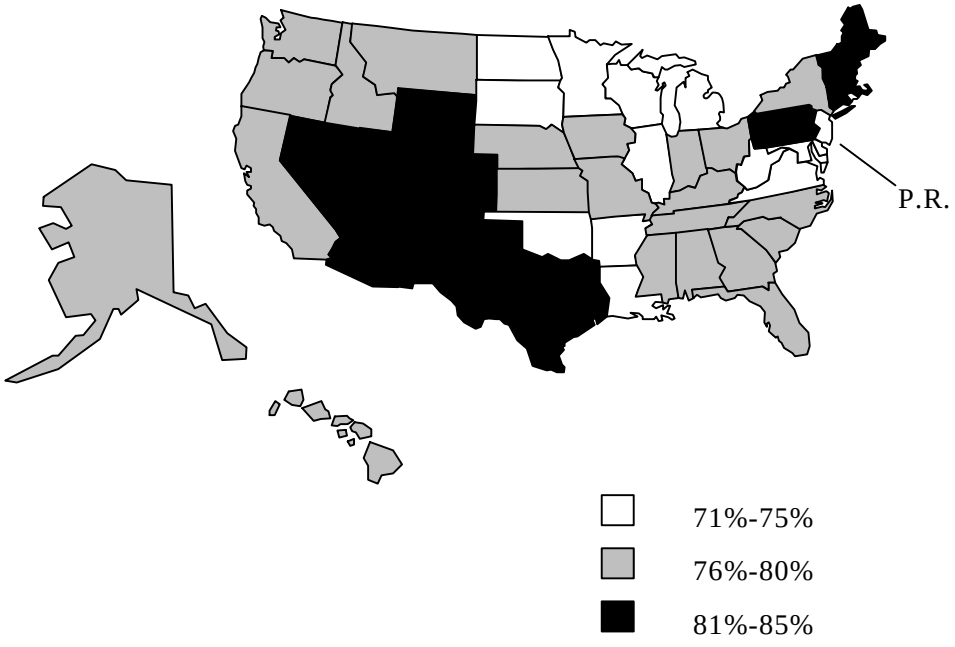


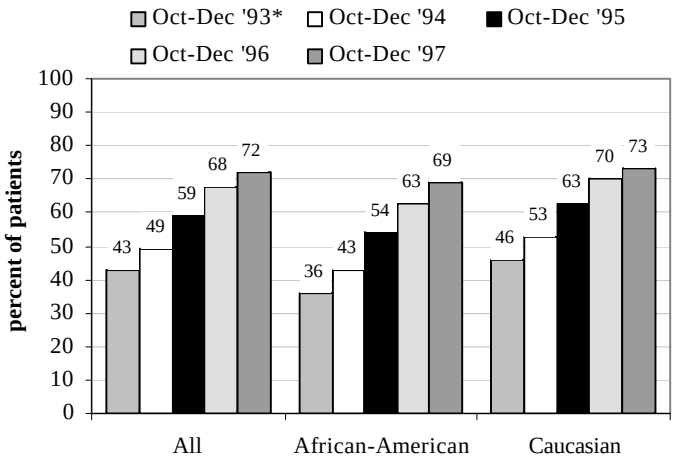
FIGURE 11b: Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving dialysis with a mean Kt/V $ 1.2, October-December 1997, by Network. 1998 ESRD Core Indicators Project.



2. October-December 1997 compared to previous study years

The average URR in October-December 1997 was 68%, an increase from previous study years. The proportion of patients receiving dialysis with a URR ≥ 65% increased significantly from 68% in late 1996 to 72% in late 1997 (FIGURE 2). This significant improvement occurred for both Caucasian and African-American patients (FIGURE 12). Nationally, this improvement means that approximately 8,000 patients were receiving hemodialysis with a URR ≥ 65% in late 1997 who would not have received this level of dialysis had they been dialyzing one year earlier (FIGURE 12).

FIGURE 12: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October-December, 1997 compared to October-December 1993,* 1994, 1995, and 1996, by race.
1998 ESRD Core Indicators Project.



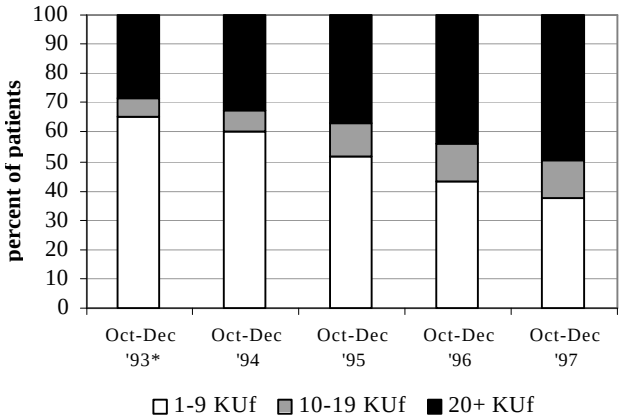
* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

Figure 13 shows the percent of adult, in-center hemodialysis patients receiving hemodialysis with a URR ≥ 65% in October-December, 1997 by dialyzer KUf value compared to October-December, 1993, 1994, 1995, and 1996.

Figure 14 shows a trend for slightly increasing dialysis session lengths from late 1993 to late 1997.

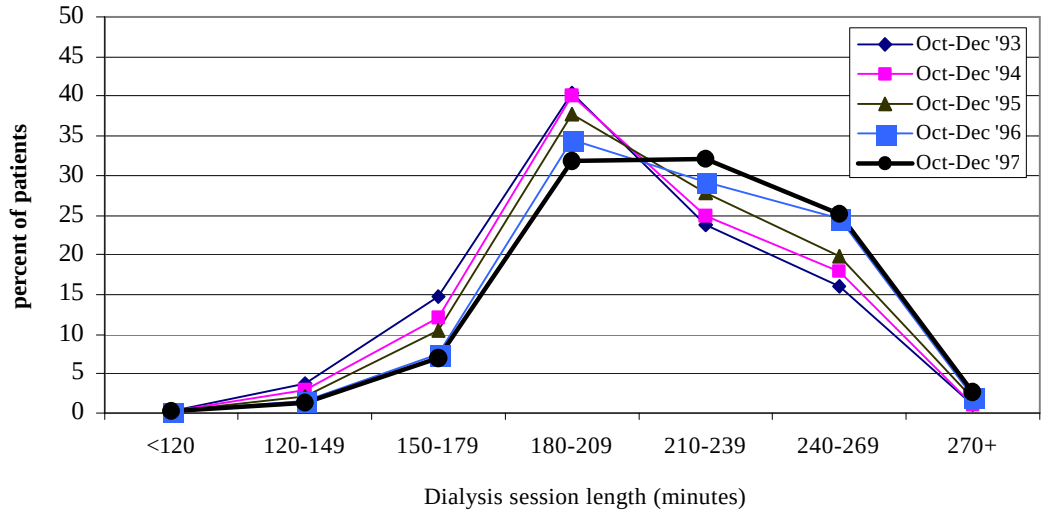
From late 1996 to late 1997 there was an increase in the proportion of patients receiving dialysis with a URR ≥ 65% in 16 of the 18 Network areas. All Network areas have shown statistically significant improvement in the percent of patients with mean URR ≥ 65% over baseline (Oct-Dec 1993)
(FIGURE 15).

FIGURE 13: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October-December 1997, by dialyzer KUf value, compared to October-December 1993*, 1994, 1995, and 1996.
1998 ESRD Core Indicators Project.



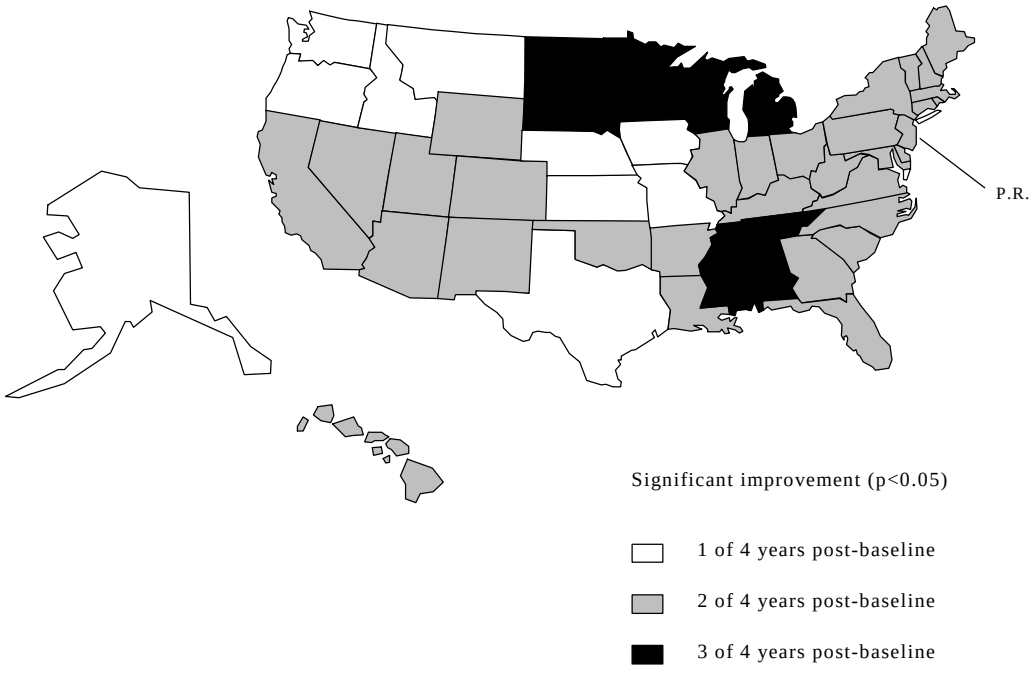
* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 14: Distribution of dialysis session length (minutes) in October-December 1997 compared to October-December 1993*, 1994, 1995, and 1996. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 15: ESRD Network areas with statistically significant improvement in the percent of adult (ages ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% from baseline*. 1998 ESRD Core Indicators Project.



*Baseline = October-December 1993 (Sixteen Network areas participated in the first ESRD Core Indicators assessment [baseline]; all Network areas participated in subsequent years.)

Table 7 depicts the Odds Ratio (95% CI) for experiencing hemodialysis with a delivered Kt/V <1.2 by several patient and practice characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a male has a 2.1 greater chance of experiencing a delivered Kt/V < 1.2 than a female (without controlling for any other variables).

TABLE 7: Independent logistic regression analyses by selected patient and practice characteristics to predict Odds Ratio (95% CI) for hemodialysis with Kt/V < 1.2. 1998 ESRD Core Indicators Project.

Characteristic	Odds Ratio (95% CI)
Gender	
Male	2.1 (1.8, 2.3)
Female (referent)	
Race	
African-American	1.1 (1.0, 1.3)
Caucasian (referent)	
Age group (years)	
18-44	1.3 (1.1, 1.5)
45+ (referent)	
Diabetes mellitus status	
DM+	1.2 (1.1, 1.3)
DM- (referent)	
Body weight (in kg)	
Highest quartile	2.7 (2.4, 3.1)
Lower 75% (referent)	
Years on dialysis	
< 1 yr	3.0 (2.6, 3.4)
1+ yrs (referent)	
Dialysis session length (minutes)	
< 210	1.3 (1.2, 1.5)
210+ (referent)	
Dialyzer KUf	
1-19	1.1 (1.0, 1.3)
20+ (referent)	

C. ANEMIA MANAGEMENT

1. October-December 1997

The distribution of hematocrit and hemoglobin values is shown in Figures 16a and 16b, respectively, for both African-American and Caucasian patients. The mean hematocrit for adult, in-center hemodialysis patients in the U.S. in the last quarter of 1997 was 33.2%. The mean hematocrit values for gender, race, age, and diagnosis are shown in Table 8. The mean hemoglobin value for patients in this sample was 10.7 gm/dL. The mean hemoglobin value was lower for females, African-Americans, patients 18-44 years old, and patients dialyzing less than one year compared to males, Caucasians, patients older than 44 years and patients dialyzing for one year or more, respectively.

The percent of patients with severe anemia (hematocrit < 28%) was 7%. The prevalence of severe anemia was higher in women compared to men, patients 18-44 years of age compared to older patients and, as reported previously (22), higher in African-Americans than Caucasians (TABLE 8). The regional variation in the percent of patients with hematocrit values < 28% is shown in Figure 17.

While the mean hematocrit varied very little from one geographic area to another (range 32.6% to 33.8%), the percent of patients with hematocrit values between 33%-36%, the percent of patients with hematocrit values > 30% and the percent of patients with hemoglobin values 11-12 gm/dL varied markedly.

Tables 9a and 9b show, by Network, race, and age group, the percent of patients receiving Epoetin with hematocrit values between 33%-36%, and the percent of patients receiving Epoetin with hemoglobin values between 11-12 gm/dL, the target range specified by the NKF DOQI Clinical Practice Guideline for the Treatment of Anemia of Chronic Renal Failure (15), respectively. The percent of all patients receiving Epoetin with hematocrit values between 33%-36% was 48% nationally and ranged from 41% to 58% by Network (TABLE 9a). The percent of all patients receiving Epoetin by race and age group, with hematocrit values between 33%-36% and hemoglobin values between 11-12 gm/dL, is shown in Figures 18a and 18b, respectively. The percent of all patients with hematocrit values > 30% was 79% nationally and ranged from 72% to 85%, by Network (FIGURE 19a). The percent of patients with hematocrit values $\geq$ 33% was 56% nationally and ranged from 50%-65%, by Network (FIGURES 19b, 20).

Because patients could receive Epoetin during one project month but not during another we were not able to correlate Epoetin use with the mean hematocrit values. Instead, we assessed Epoetin use at the time of each of the 20,272 hematocrit determinations reported in this Project. Overall, Epoetin was being used 96% of the time when a hematocrit value was determined (TABLE 10). Recombinant human erythropoietin was being used 97% of the time when the hematocrit values were <28%, 98% of the time when the hematocrit ranged from 28-32% and from 33-36%, and 76% of the time when the hematocrit values were > 36% (TABLE 10). The use of Epoetin and the average dose (units per kg) at the time of hematocrit determinations for gender, race, age, and diagnosis groups are also shown in Table 10.

FIGURE 16a: Distribution of mean hematocrit values for adult (aged $ 18 years), in-center hemodialysis patients in the U.S., October-December 1997, by race.
1998 ESRD Core Indicators Project.

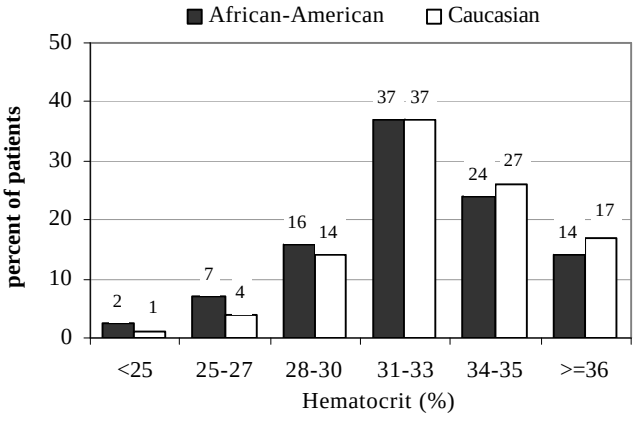


FIGURE 16b: Distribution of mean hemoglobin values for adult (aged $ 18 years), in-center hemodialysis patients in the U.S., October-December 1997, by race. 1998 ESRD Core Indicators Project.

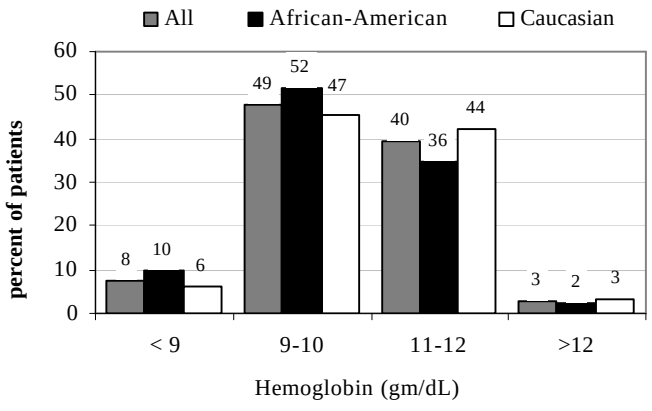


FIGURE 17: Percent of adult (aged $ 18 years) in-center hemodialysis patients with hematocrit values < 28%, October-December 1997, by Network.
1998 ESRD Core Indicators Project.

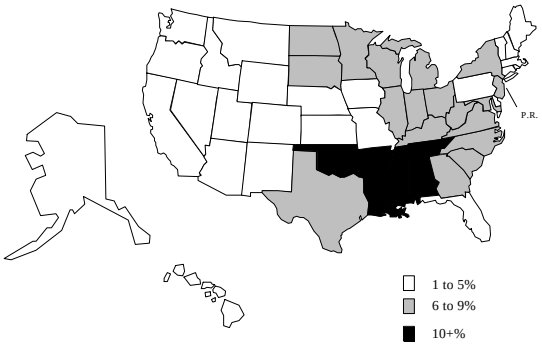


FIGURE 18a: Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving Epoetin with mean hematocrit values between 33%-36%, October-December 1997, by age and race.1998 ESRD Core Indicators Project.

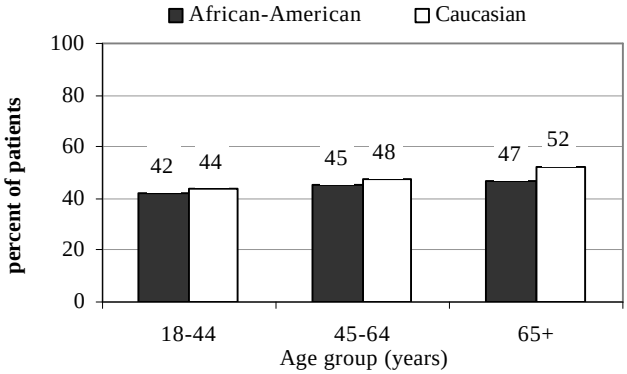
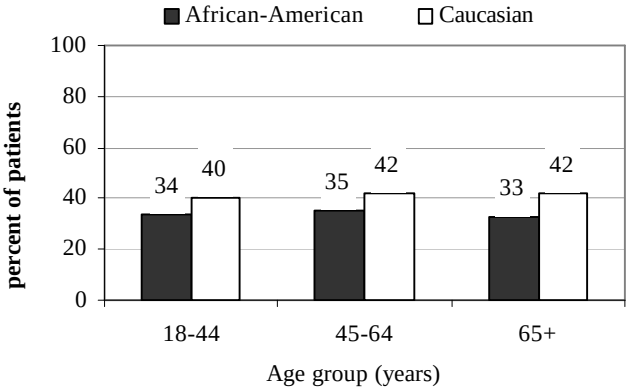


FIGURE 18b: Percent of adult (aged $ 18 years), in-center hemodialysis patients receiving Epoetin with mean hemoglobin values between 11-12 gm/dL, October-December 1997, by age and race.
1998 ESRD Core Indicators Project.



During this study period, data were collected on additional measures useful for anemia management. The national average percent transferrin saturation for the patients in the sample was 29.1% and ranged from 27.0-32.3% among the eighteen Network areas (TABLE 11). Table 11 also provides the percent of patients with transferrin saturation values $\geq$ 20% nationally (70%) and by Network area, ranging from 62% to 75%.

The national average ferritin concentration for the patients in the sample was 505 ng/mL and ranged from 426 to 599 ng/mL among the eighteen Network areas. The percent of patients with ferritin concentrations $\geq$ 100 ng/mL nationally was 81%, ranging from 73% to 89% (TABLE 11).

The percent of patients with intravenous (IV) iron prescribed nationally was 57%, ranging from 48% to 67% among the eighteen Network areas (TABLE 11).

For the subset of patients with both transferrin saturation <20% and ferritin concentration < 100 ng/mL (n=399 or 6%), only 40% were prescribed IV iron at least once during the three month study period.

Of the patients prescribed Epoetin, 90% were prescribed Epoetin by the IV route; 11% by the subcutaneous route (groups not mutually exclusive). Prescribed subcutaneous administration, the route recommended by the NKF-DOQI clinical practice guidelines for the treatment of anemia (15), ranged from 3%-31% among the eighteen Network areas (TABLE 11).

TABLE 8: Hematocrit values for adult (aged $\geq$18 years), in-center hemodialysis patients in the U.S., October-December 1997, by patient characteristics. 1998 ESRD Core Indicators Project

Patient Characteristic	mean hematocrit (%)	% of patients with hematocrit values			
		< 28%	28-32%	33-36%	> 36%
TOTAL	33.2	7	37	47	10
GENDER					
Men	33.5	6	34	48	12
Women	32.9	8	39	46	7
RACE					
American Indian/ Alaska Native	33.6	5	35	49	11
Asian/Pacific Islander	33.6	3	36	53	7
African-American	32.9	9	38	44	9
Caucasian	33.4	6	36	49	10
Other/Unknown	33.0	7	39	44	10
AGE GROUP (years)					
18-44	32.8	11	39	41	10
45-64	33.3	7	36	45	12
65+	33.3	5	36	50	8
DIAGNOSIS					
Diabetes mellitus	33.1	6	38	47	8
Hypertension	33.2	7	37	48	9
Glomerulonephritis	33.4	6	34	48	11
Other/Unknown	33.3	8	36	44	12

*note: percents may not add up to 100% due to rounding.

TABLE 9a: Percent of adult (aged$18 years), in-center hemodialysis patients receiving Epoetin with hematocrit values between 33-36%, October-December 1997, by age, race, and Network. 1998 ESRD Core Indicators Project.

Patient Characteristic	NETWORK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ALL	48	46	44	53	51	46	49	45	45	47	46	46	41	46	46	57	51	58
RACE																		
African-American	41	38	38	45	51	44	48	44	40	45	51	40	44	43	46	68	58	56
Caucasian	49	52	48	56	51	52	50	45	48	51	44	48	34	48	46	55	48	60
AGE GROUP (years)																		
18-44																		
African-American	42	45	19	42	37	37	44	38	32	52	49	47	44	41	36	67	60	59
Caucasian	38	52	53	64	58	37	41	36	47	44	47	44	39	32	34	54	37	39
45-64																		
African-American	45	31	45	47	56	42	48	44	37	44	56	38	44	42	50	60	54	56
Caucasian	45	40	39	53	38	57	46	46	42	56	34	44	34	52	48	54	61	68
65+																		
African-American	37	44	40	46	52	47	51	51	46	43	43	41	43	46	57	75	59	54
Caucasian	53	58	54	57	58	55	52	47	51	50	45	51	31	49	49	56	47	62

TABLE 9b: Percent of adult (aged$18 years), in-center hemodialysis patients receiving Epoetin with hemoglobin values between 11-12 gm/dL, October-December 1997, by age, race, and Network. 1998 ESRD Core Indicators Project.

Patient Characteristic	NETWORK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ALL	38	37	34	40	38	34	42	38	40	36	35	44	31	34	46	40	51	51
RACE																		
African-American	28	32	36	33	34	31	39	36	32	36	33	34	27	28	50	30	56	48
Caucasian	40	40	36	43	44	37	42	40	44	38	37	49	33	38	44	41	48	52
AGE GROUP (years)																		
18-44																		
African-American	42	34	27	32	27	40	36	38	23	48	32	33	24	25	36	44	60	47
Caucasian	40	39	40	40	54	26	41	32	47	38	37	44	44	36	30	46	47	42
45-64																		
African-American	24	32	38	33	37	30	44	36	35	39	34	35	31	29	62	27	50	52
Caucasian	47	35	24	42	38	36	39	46	50	44	32	48	34	40	50	40	52	54
65+																		
African-American	26	31	38	35	34	29	37	36	33	26	31	32	26	30	57	25	55	42
Caucasian	36	42	45	44	45	42	43	38	41	35	39	51	28	36	46	40	47	55

FIGURE 19a: Percent of adult (aged $18 years), in-center hemodialysis patients with mean hematocrit values > 30%, October-December 1997, by Network. 1998 ESRD Core Indicators Project.

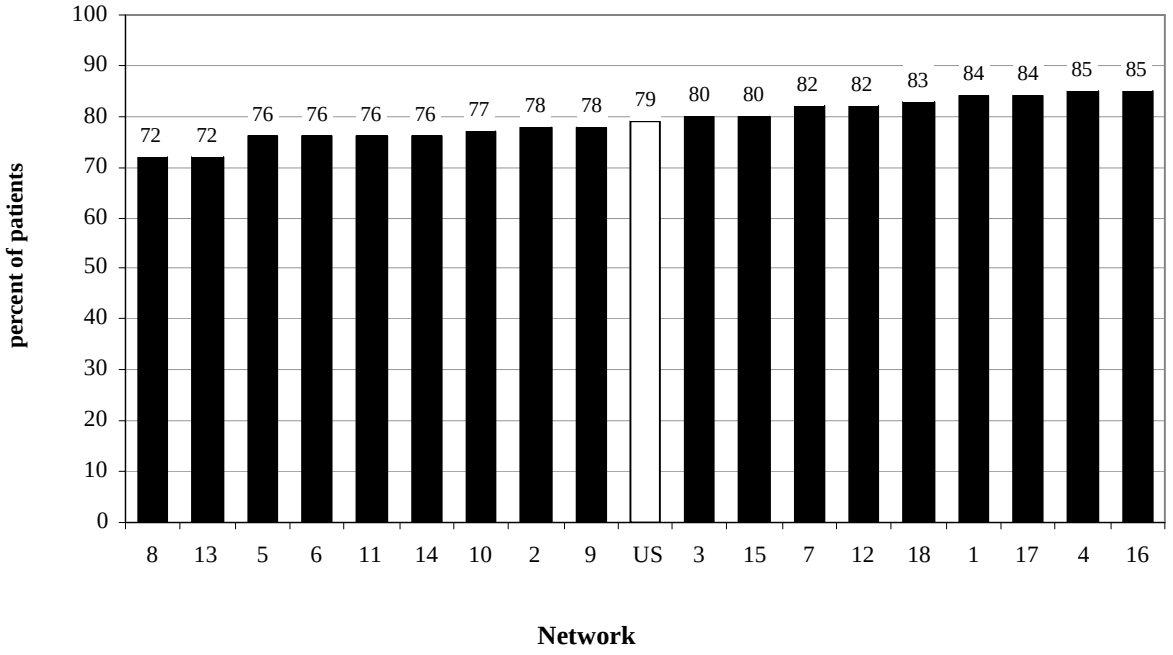


FIGURE 19b: Percent of adult (aged $18 years), in-center hemodialysis patients with mean hematocrit values $ 33%, October-December 1997, by Network. 1998 ESRD Core Indicators Project.

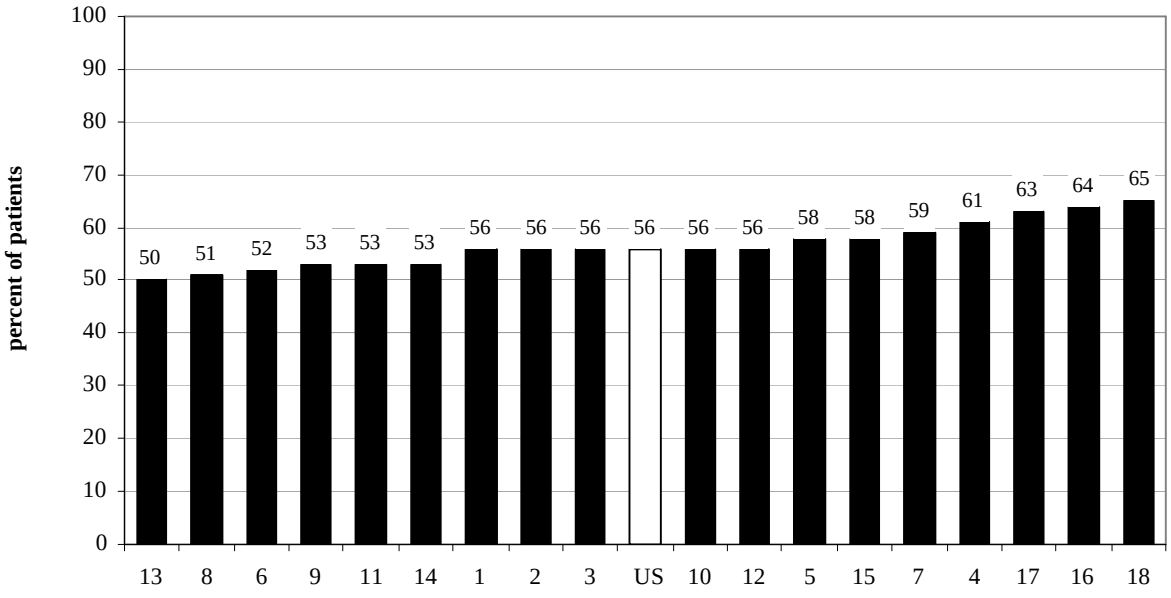


FIGURE 20: Percent of adult (aged $18 years), in-center hemodialysis patients with mean hematocrit value$ 33%, October-December 1997, by Network. 1998 ESRD Core Indicators Project.

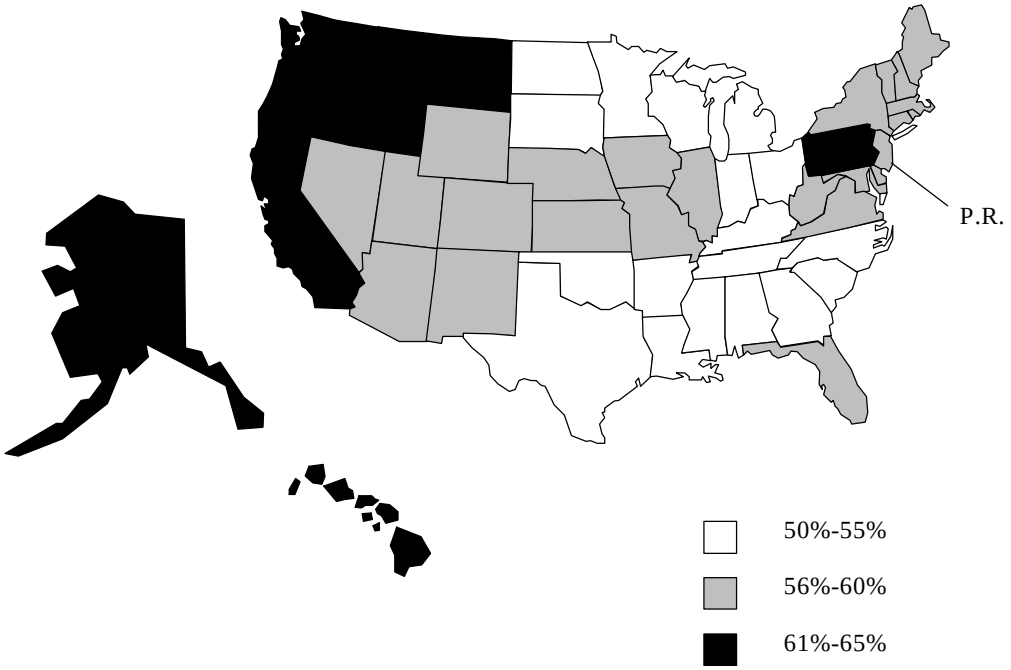


TABLE 10: Percent of adult (aged $18 years), in-center hemodialysis patients in the U.S. receiving Epoetin at time hematocrit was drawn and the average Epoetin dose, October-December 1997, by patient characteristics.
1998 ESRD Core Indicators Project

Patient Characteristic	Overall %	Hematocrit values <28% (dose*)	28-32% (dose*)	33-36% (dose*)	>36% (dose*)
TOTAL	96 (65)	97 (92)	98 (70)	98 (56)	76 (61)
GENDER					
Men	94 (60)	96 (85)	98 (66)	97 (53)	71 (56)
Women	98 (69)	97 (98)	99 (73)	98 (60)	84 (67)
RACE					
American Indian/Alaska Native	94 (53)	100 (101)	100 (57)	94 (46)	75 (42)
Asian/Pacific Islander	98 (69)	100 (119)	100 (66)	99 (69)	73 (54)
African-American	96 (66)	96 (95)	99 (71)	98 (56)	76 (57)
Caucasian	95 (64)	98 (87)	98 (69)	97 (56)	74 (65)
Other/Unknown	96 (65)	95 (86)	97 (70)	98 (58)	87 (56)
AGE GROUP (years)					
18-44	95 (70)	96 (98)	99 (72)	98 (60)	65 (63)
45-64	95 (63)	96 (85)	99 (69)	97 (54)	73 (57)
65+	97 (64)	99 (92)	98 (69)	98 (57)	83 (63)
DIAGNOSIS					
Diabetes mellitus	97 (61)	98 (72)	98 (66)	98 (54)	82 (58)
Hypertension	96 (66)	96 (103)	99 (70)	98 (58)	79 (60)
Glomerulonephritis	95 (66)	95 (98)	99 (69)	98 (58)	71 (70)
Other/Unknown	94 (69)	98 (104)	98 (77)	97 (56)	66 (60)

*dose=units per Kg

TABLE 11: Regional variation for various anemia management measures for adult (ages $ 18 years), in-center hemodialysis patients, and the percent of patients with mean hematocrit values $33%, October-December 1997, national and by Network. 1998 ESRD Core Indicators Project.

	NETWORK																		
Anemia Management Measure:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
Percent of patients with hematocrit $33%	**56**	**56**	**56**	**61**	**58**	**52**	**59**	**51**	**53**	**56**	**53**	**56**	**50**	**53**	**58**	**64**	**63**	**65**	**56**
Average Transferrin Saturation (%)	27.0	27.1	29.4	28.2	27.8	30.8	29.3	32.3	28.1	31.9	29.0	27.8	30.2	28.6	30.8	30.1	27.0	28.7	29.1
Percent of patients with Transferrin Saturation $ 20%	71	66	68	70	69	73	72	70	64	75	68	62	69	74	73	68	69	74	70
Average Ferritin concentration (ng/mL)	459	426	465	491	462	599	578	525	498	432	479	473	524	524	493	490	563	521	505
Percent of patients with Ferritin concentration $100 ng/mL	76	73	80	79	80	85	81	84	79	77	83	83	84	86	80	78	89	81	81
Percent of patients with IV Iron Prescribed	59	48	60	54	52	61	59	58	67	61	61	51	63	62	54	57	53	49	57
Percent of patients * with subcutaneous Epoetin prescribed	5	6	9	7	7	6	3	10	31	16	17	18	13	13	6	21	12	4	11

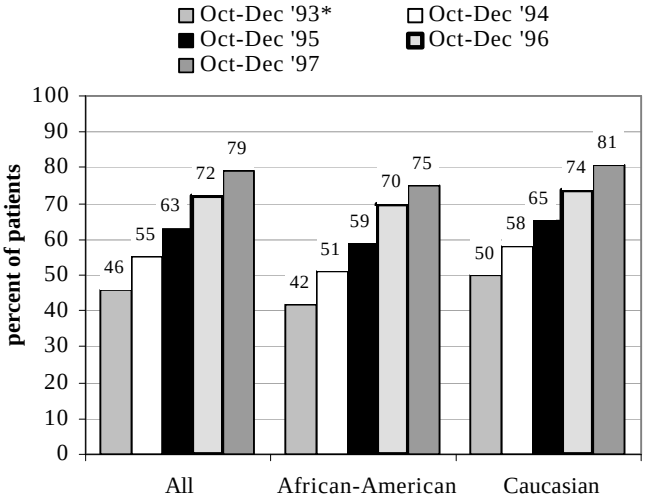
*among patients receiving Epoetin

2. <u>October-December 1997 compared to previous study periods</u>.

The average hematocrit from October-December 1996 to October-December 1997 increased from 32.7% to 33.2%, and the percentage of patients with a mean hematocrit > 30% increased significantly from 72% to 79% (FIGURES 4, 5, 21). This significant improvement occurred towards a goal of the National Anemia Cooperative Project for both Caucasian and African-American patients.

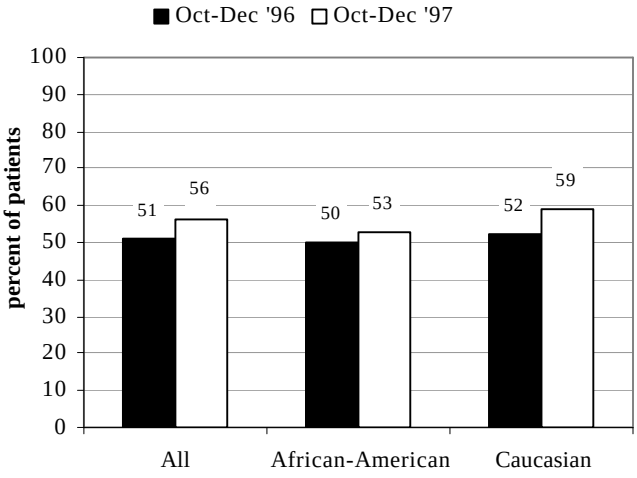
In addition to the improvement in the percentage of patients with hematocrit >30%, and ≥33% (FIGURE 22), there was also a decrease in the percentage of patients with severe anemia (hematocrit < 28%). In October-December 1996, 12% of African-American patients and 9% of Caucasian patients had severe anemia, while in October-December 1997, 9% of African-American patients and 6% of Caucasian patients had severe anemia.

FIGURE 21: Percent of adult (age ≥18 years), in-center hemodialysis patients with mean hematocrit >30%, October-December 1997 compared to October-December 1993*, 1994, 1995, and 1996, by race. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 22: Percent of adult (age ≥18 years), in-center hemodialysis patients with hematocrit values ≥33%, by race, October-December 1997 compared to October-December 1996.
1998 ESRD Core Indicators Project.



From late 1996 to late 1997 there was an increase in the proportion of patients with hematocrit >30% in 17 of the 18 Network areas, and in 11 of these areas the increase was statistically significant.

Figure 23 depicts the trend in Epoetin dosing (units/kg) from late 1996 to late 1997. Subcutaneous Epoetin doses for 1996 are not depicted in this figure due to the small number of patients receiving Epoetin by this route in 1996 (n=513). In late 1997, subcutaneous Epoetin doses were systematically lower than the intravenous Epoetin doses at all hematocrit categories examined.

Figure 24 depicts iron stores status for the sampled patients in late 1997 compared to late 1996. Overall, 57% of patients were prescribed IV iron in late 1997 compared to 51% in late 1996. Within the subgroup of patients with transferrin saturation <20% and ferritin concentration <100 ng/mL, 40% and 37% of patients were prescribed IV iron at least once over the three month study period in late 1997 and late 1996, respectively.

FIGURE 23: Mean Epoetin dose (units/kg) for adult (age ≥ 18 years), in-center hemodialysis patients, by hematocrit category and route of administration, October-December 1997 compared to October-December 1996.
1998 ESRD Core Indicators Project.

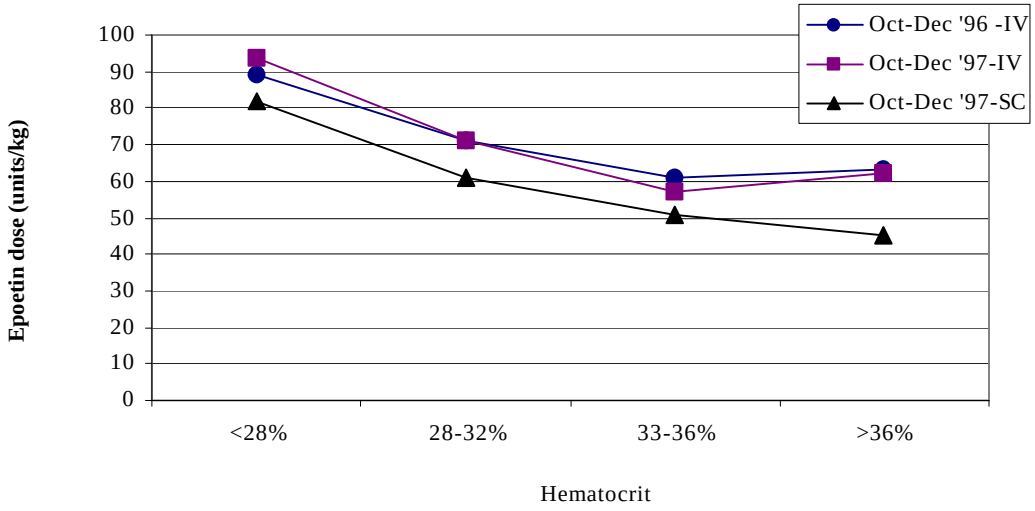
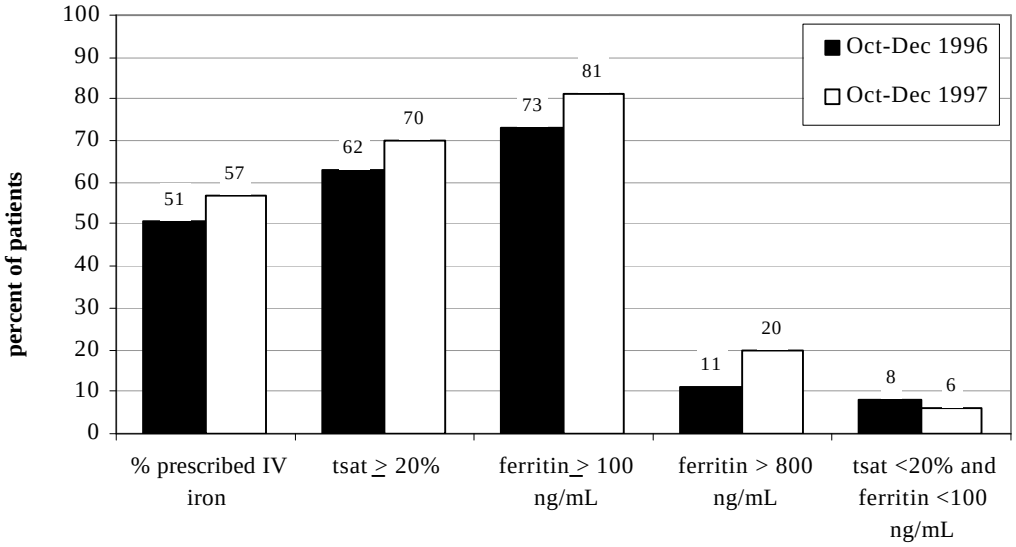


FIGURE 24: Percent of adult (≥ 18 years) in-center hemodialysis patients prescribed intravenous iron, with transferrin saturation ≥ 20%, ferritin concentration ≥ 100 ng/mL and >800 ng/mL, and with both transferrin saturation <20% and ferritin concentration <100 ng/mL, October-December 1997 compared to October-December 1996.
1998 ESRD Core Indicators Project.



D. SERUM ALBUMIN

1. October-December 1997

The two commonly used laboratory methods for determining serum albumin values, bromcresol green (BCG) and bromcresol purple (BCP), have been reported to yield systematically different results. (16) Therefore, we assessed the serum albumin values reported for these two methods separately. As expected, the values determined by the BCP method were systematically lower than those determined by the BCG method (TABLE 12).

The mean serum albumin value for patients whose value was determined by the BCG method (N=5,878) was 3.8 gm/dL, and by the BCP method (N=1,169) was 3.6 gm/dL. The mean serum albumin values for gender, race, age, and diagnosis groups are shown in Table 12.

Serum albumin values <3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin level. (23) Since the percent of serum albumin values <3.2 gm/dL by the BCP method was the same as the percent of serum albumin values <3.5 gm/dL by the BCG method (17%), we also defined a BCP result <3.2 gm/dL as an indicator of inadequate serum albumin level. Figure 25 displays the distribution of serum albumin values by laboratory method.

Table 12 also shows the percent of patients by gender, race, age, and diagnosis groups with mean serum albumin values $\geq$ 3.5 gm/dL by the BCG method or $\geq$3.2 gm/dL by the BCP method. The percent of patients with mean serum albumin values $\geq$ 3.5 gm/dL by the BCG or $\geq$ 3.2 gm/dL by the BCP method tended to be higher for African-Americans than for Caucasians, for men than for women, and for patients 18-44 years old than for patients 45 years or older (TABLE 12, FIGURE 26). The percent of patients in each Network area, by race and age group, with mean serum albumin values $\geq$ 3.5 gm/dL by BCG or $\geq$ 3.2 gm/dL by BCP methods is shown in Table 13; the percent ranged from 76% to 87%.

Nationally, 83% of patients had mean serum albumin values $\geq$ 3.5 gm/dL by BCG or $\geq$ 3.2 gm/dL by BCP methods.

2. October-December 1997 compared to previous study periods

There was no clinically important change or improvement in the proportion of adult, in-center hemodialysis patients with sub-optimal serum albumin levels during October-December 1997 compared to previous study periods.

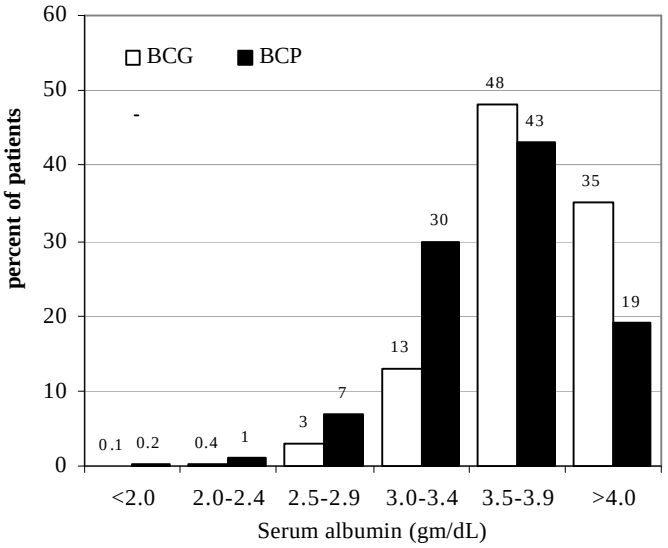
Figure 27 shows the percent of patients with mean serum albumin values $\geq$ 3.5gm/dL by the BCG method or $\geq$ 3.2gm/dL by the BCP method during October-December 1997 compared to October-December 1993, 1994, 1995, and 1996.

TABLE 12: Serum albumin values (gm/dL) for adult (aged $\geq$18 years), in-center hemodialysis patients in the U.S., Oct-Dec 1997, by patient characteristics and by laboratory method*. 1998 ESRD Core Indicators Project.

	BCG		BCP	
PATIENT CHARACTERISTIC	mean	% $\geq$ 3.5 gm/dL	mean	% $\geq$ 3.2 gm/dL
TOTAL	3.8	83	3.6	83
GENDER				
Men	3.9	85	3.6	86
Women	3.8	82	3.6	81
RACE				
American Indian/ Alaska Native	3.7	78	3.5	76
Asian/Pacific Islander	3.8	84	3.6	89
African-American	3.8	85	3.7	85
Caucasian	3.8	83	3.6	81
Other/Unknown	3.8	80	3.6	88
AGE GROUP (years)				
18-44	3.9	88	3.7	89
45-64	3.8	84	3.6	84
65+	3.8	82	3.6	82
DIAGNOSIS				
Diabetes mellitus	3.7	79	3.5	80
Hypertension	3.9	87	3.7	89
Glomerulonephritis	3.9	88	3.7	87
Other/Unknown	3.9	85	3.6	82

*laboratory methods: BCG = bromcresol green; BCP = bromcresol purple

FIGURE 25: Distribution of serum albumin values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1997, by laboratory method*.
1998 ESRD Core Indicators Project.



* BCG = Bromcresol green; BCP = Bromcresol purple

FIGURE 26: Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean serum albumin ≥3.5 gm/dL (BCG method) or ≥3.2 gm/dL (BCP method), October-December 1997, by race and gender.
1998 ESRD Core Indicators Project.

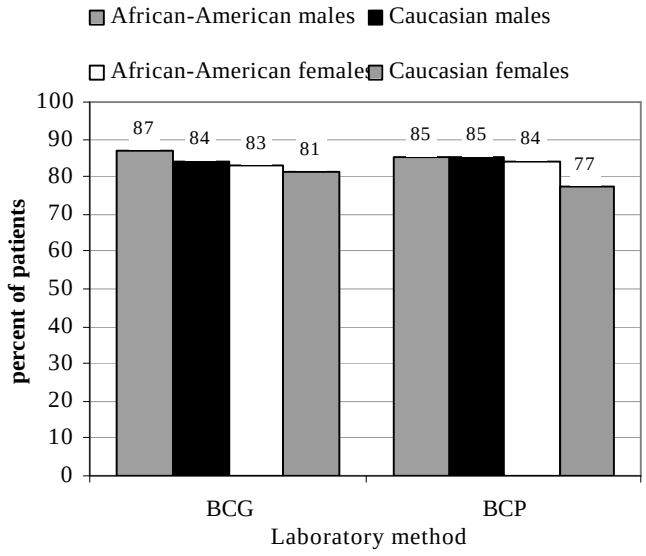
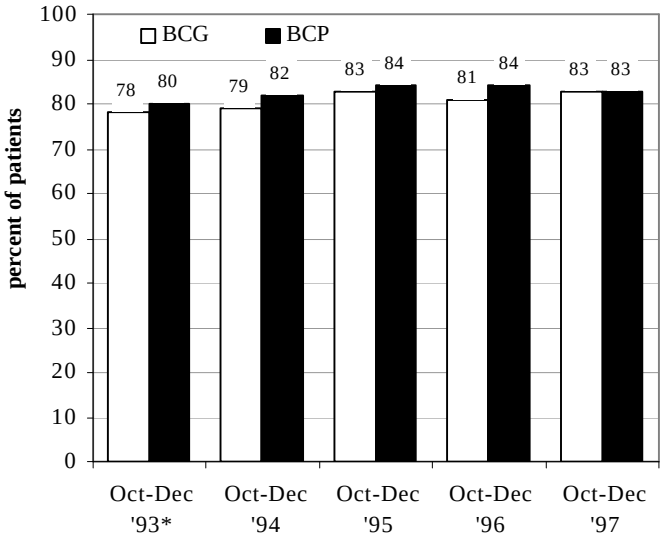


FIGURE 27: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), October-December 1997 compared to October-December 1993*, 1994, 1995, and 1996. 1998 ESRD Core Indicators Project.



* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all 18 Network areas participated in subsequent years.

TABLE 13: Percent of adult (aged $18 years), in-center hemodialysis patients with serum albumin $ 3.5 gm/dL (BCG method) or $ 3.2 gm/dL (BCP method), October-December 1997, by age, race, and Network. 1998 ESRD Core Indicators Project.

Patient Characteristic	NETWORK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ALL	79	84	83	86	84	85	84	85	86	78	79	83	82	84	83	76	85	87
RACE																		
African-American	79	83	84	87	83	86	85	86	86	80	84	84	86	89	88	79	88	87
Caucasian	79	86	84	86	84	82	84	84	86	78	75	81	77	82	83	75	85	87
AGE GROUP (years)																		
18-44																		
African-American	93	88	79	97	82	91	84	85	100	75	90	100	92	88	100	100	71	90
Caucasian	87	96	94	84	85	90	86	87	95	88	93	79	75	76	80	83	95	92
45-64																		
African-American	76	80	88	82	89	86	91	89	88	86	83	76	89	88	90	76	100	87
Caucasian	80	82	90	88	77	68	84	80	86	72	74	81	77	85	83	69	92	88
65+																		
African-American	74	83	84	86	78	84	77	84	80	75	82	83	82	91	67	69	90	88
Caucasian	77	86	80	85	89	88	85	85	82	79	73	82	77	83	84	76	79	85

VII. PERITONEAL DIALYSIS PATIENTS

A. SYNOPSIS

- Purpose of Project: the ultimate purpose of the ESRD Core Indicators Project is to assist providers of ESRD services to improve care provided to ESRD patients. The immediate purposes of the 1998 project were:

  To compare the prevalence of important clinical characteristics of adult (age ≥ 18 years), peritoneal dialysis patients in the U.S. in Nov-Dec 1997 & Jan-Apr 1998 to the prevalence of those characteristics in Nov-Dec 1994 & Jan-Apr 1995, Nov-Dec 1995 & Jan-Apr 1996, and Nov-Dec 1996 & Jan-Apr 1997; AND, To identify opportunities to improve care for those patients.

- Method Used: A national random sample of adult, peritoneal dialysis patients who were alive on December 31, 1997 was selected (sample size 1499).

ESRD facilities, with assistance from ESRD Networks, submitted to HCFA clinical information about these patients for the time period Nov-Dec 1997 & Jan-Apr 1998.

- Initial Findings: Data were submitted for 1381 (92%) of the patients in the sample. Highlights from the initial findings include:

IMPROVEMENT OCCURRED

- Adequacy of dialysis was assessed at least once for approximately 81% of the sampled patients during the 1998 study period (Nov-Dec '97 & Jan-Apr '98), compared to 75% during the 1997 study period (Nov-Dec '96 & Jan-Apr '97) (FIGURE 28).
- There was an improvement in the delivered adequacy of dialysis for sampled patients as measured by weekly Kt/V urea and weekly creatinine clearance values during the 1998 study period compared to the 1996 and 1997 study periods (FIGURES 7a, 7b, 29a, 29b, TABLE 14).
- There was a two percentage point increase in the percentage of peritoneal dialysis patients with mean hematocrit values > 30% from the 1997 study period (76%) to the 1998 study period (78%) (FIGURE 31).

OPPORTUNITIES TO IMPROVE

- The adequacy of dialysis was not assessed during the 1998 study period for an estimated 19% of the sampled peritoneal dialysis patients.
- A substantial percentage of sampled patients did not have weekly adequacy values meeting DOQI guidelines.
- 22% of the sampled peritoneal dialysis patients had mean hematocrit values < 31% in the 1998 study period.
- 43% of the sampled peritoneal dialysis patients had mean serum albumin values < 3.5 gm/dL (BCG method) or < 3.2 gm/dL (BCP method) in the 1998 study period.
- Approximately one in four of the sampled peritoneal dialysis patients had systolic blood pressure > 150 mmHg (FIGURE 36).

- Next Steps: Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to document further improved care for ESRD patients in 1999 and 2000.

B. ADEQUACY OF DIALYSIS

1. November 1997-April 1998

Using values that were abstracted from medical records of peritoneal dialysis patients, it was possible to calculate at least one of the adequacy measures (weekly Kt/V urea or weekly creatinine clearance) for 1010 (73%) of the 1381 patients during the 1998 study period. Of the 371 (27%) medical records with insufficient information to calculate an adequacy measure, 105 (28%) of these medical records had at least either one weekly Kt/V urea value (101 records) or one weekly creatinine clearance value (88) recorded during the 1997 study period. Approximately 81% of peritoneal dialysis patients had adequacy of dialysis assessed at least once during this study period.

Forty-five percent of CAPD and 42% of cycler patients had calculated weekly Kt/V urea values that met recommended DOQI guidelines, 41% of CAPD and 32% of cycler patients had calculated weekly creatinine clearance values that met recommended DOQI guidelines (TABLE 14).

2. November 1997-April 1998 compared to previous study years

The adequacy of dialysis was assessed for approximately 81% of adult peritoneal dialysis patients at least once during the 1998 six-month study period (Nov 1997 - Apr 1998), compared to only 66% during the 1995 study period, and 69% during the 1996 study period, and 75% during the 1997 study period (FIGURE 28).

In addition to increasing numbers of patients having an adequacy measure performed during the six month study period, both CAPD and cycler patients have experienced improved clearances from Nov '94-Apr '95 to Nov '97-Apr '98 (TABLE 14).

Figures 29a and 29b depict the improvement in the delivered adequacy of dialysis for CCPD patients from the 1996-1998 study periods. Mean weekly Kt/V urea and weekly creatinine clearance values for all cycler patients increased over this time period (TABLE 14) A similar improvement in adequacy measures occurred for CAPD patients (FIGURES 7a and 7b, TABLE 14).

FIGURE 28: Estimated percent of adult (aged ≥ 18 years) peritoneal dialysis patients with at least one adequacy assessment during Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

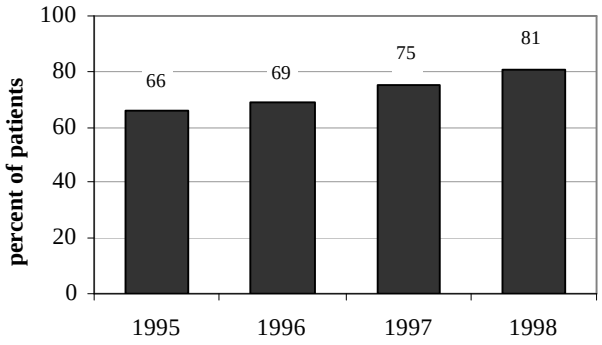


FIGURE 29a: Distribution of weekly Kt/V urea values for adult (aged ≥ 18 years) CCPD patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

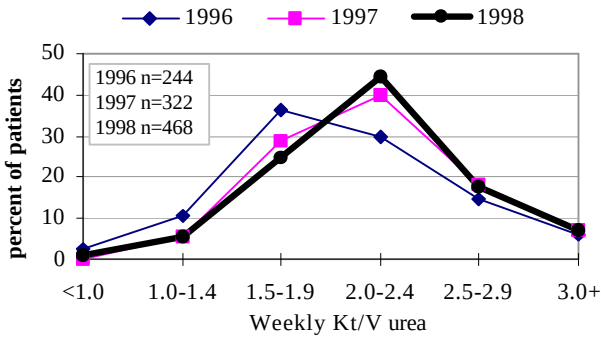


FIGURE 29b: Distribution of weekly creatinine clearance values (L/week/1.73m^2) for adult (aged ≥ 18 years) CCPD patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

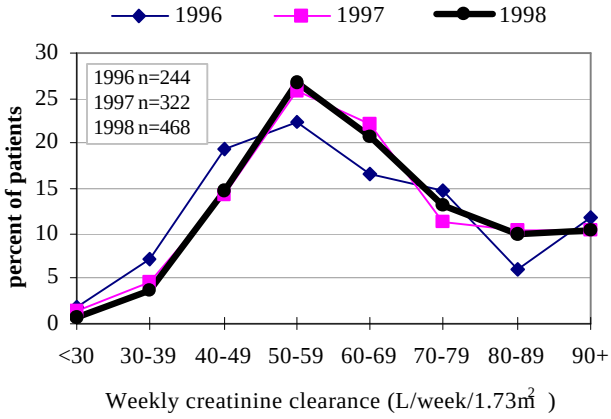


TABLE 14: Percent of adult (aged $ 18 years) peritoneal dialysis patients with weekly adequacy values meeting DOQI guidelines, mean (± SD), and median adequacy values Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96 and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

	Nov '94 -Apr '95*	Nov '95 -Apr '96		Nov '96 - Apr '97		Nov '97 - Apr '98	
Adequacy Measure	**CAPD (n=951)**	**CAPD (n=796)**	**Cyclers (n=402)**	**CAPD (n=757)**	**Cyclers (n=521)**	**CAPD (n=804)**	**Cyclers (n=663)**
Weekly Kt/V urea							
% meeting DOQI	23	27	28	36	36	45	42
mean (± S.D.)	1.91 (±0.8)	2.00 (±0.6)	2.12 (±0.6)	2.12 (±0.6)	2.24 (±0.6)	2.20 (±0.6)	2.25 (±0.6)
median	1.90	1.90	2.00	2.00	2.20	2.10	2.20
Weekly Creatinine Clearance							
% meeting DOQI	21	30	26	34	33	41	32
mean (± S.D.)	61.5 (±31.6)	64.3 (±23.6)	63.4 (±23.5)	65.8 (±24.7)	67.4 (±24.4)	67.8 (±22.6)	66.5 (±22.0)
median	57.2	59.6	59.0	60.7	62.2	63.0	60.8

DOQI guidelines:

For CAPD patients: Kt/V urea $ 2.0; creatinine clearance $ 60 L/week/1.73m^2

For Cycler patients with daytime dwell: Kt/V urea $ 2.1; creatinine clearance $ 63 L/week/1.73m^2

For nighttime Cycler patients (no daytime dwell): Kt/V urea $ 2.2; clearance $ 66 L/week/1.73m^2

*Cycler data for Nov '94-Apr '95 not shown due to low number of cycler patients during that study period.

C. ANEMIA MANAGEMENT

1. November 1997-April 1998

The average hematocrit for adult peritoneal dialysis patients in the sample was 33.8%. The average hemoglobin for these patients was 11.1 gm/dL; the distribution of hemoglobin values is shown in Figure 30. Overall, 44% of patients receiving Epoetin had hematocrit values between 33% and 36%, the range targeted by the NKF DOQI Clinical Practice Guideline for the Treatment of Anemia. (15) A smaller percentage of women, African-Americans, and younger (aged 18-44 years) patients receiving Epoetin had hematocrit values between 33%-36% compared to men, Caucasians, and older (≥ 45 years) patients, respectively (TABLE 15).

The mean hematocrit values and the proportion of patients within different hematocrit categories for gender, race, age, and diagnosis are shown in Table 15. The prevalence of severe anemia (hematocrit <28%) was 8%. The prevalence of severe anemia was significantly higher in women compared to men, African Americans compared to Caucasians and for patients 18-44 years old compared to older patients (TABLE 15).

The average transferrin saturation for the patients in this sample was 27.9%, and 65% of patients had transferrin saturations ≥ 20%. The average ferritin concentration for this population was 364 ng/mL, with 72% of patients having ferritin concentration ≥100 ng/mL. Eighty-seven patients (6%) had both a transferrin saturation < 20% and a ferritin concentration < 100 ng/mL.

Because patients could receive Epoetin during one project two-month period but not during another, we were not able to correlate Epoetin use with the mean hematocrit values. Instead, we assessed Epoetin use at the time of each of the 3765 hematocrit determinations reported for this study period. Overall, Epoetin was being used 86% of the time when a hematocrit value was determined. Epoetin was used 97% of the time when the hematocrit values were < 28%, 98% when the hematocrit ranged from 28-32%, 91% of the time when the hematocrit ranged from 33-36%, and 49% of the time when the hematocrit values were > 36%.

Iron use was assessed during this study period. Iron by either the oral or intravenous route was prescribed at least one of the two-month study periods for 79% of the patients in this sample, and throughout the six- month period for 58% of the patients. Of the patients prescribed iron, 93% were prescribed oral iron and 17% were prescribed intravenous iron (not mutually exclusive categories). Among those patients with transferrin saturation < 20% and ferritin concentration < 100 ng/mL, 85% were prescribed either oral or IV iron at least once during the six months and 71% received some iron all six months. Thirteen percent of these patients were prescribed IV iron at least once during the six month study period.

2. November 1997-April 1998 compared to previous study periods

The average hematocrit increased from 32.5% during the 1995 study period to 33.8% during the 1998 study period (FIGURE 6). The percentage of peritoneal dialysis patients with mean hematocrit values >30% increased from 64% to 78% over the four study periods (FIGURE 31). A greater percentage of Caucasians compared to African Americans had a mean hematocrit value > 30% each study period.

The distributions of transferrin saturation values (%) and ferritin concentrations (ng/mL) were similar for the Nov '96-Apr '97 and Nov '97-Apr '98 study periods (FIGURES 32a, 32b).

FIGURE 30: Distribution of hemoglobin values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '97-Apr '98. 1998 ESRD Core Indicators Project.

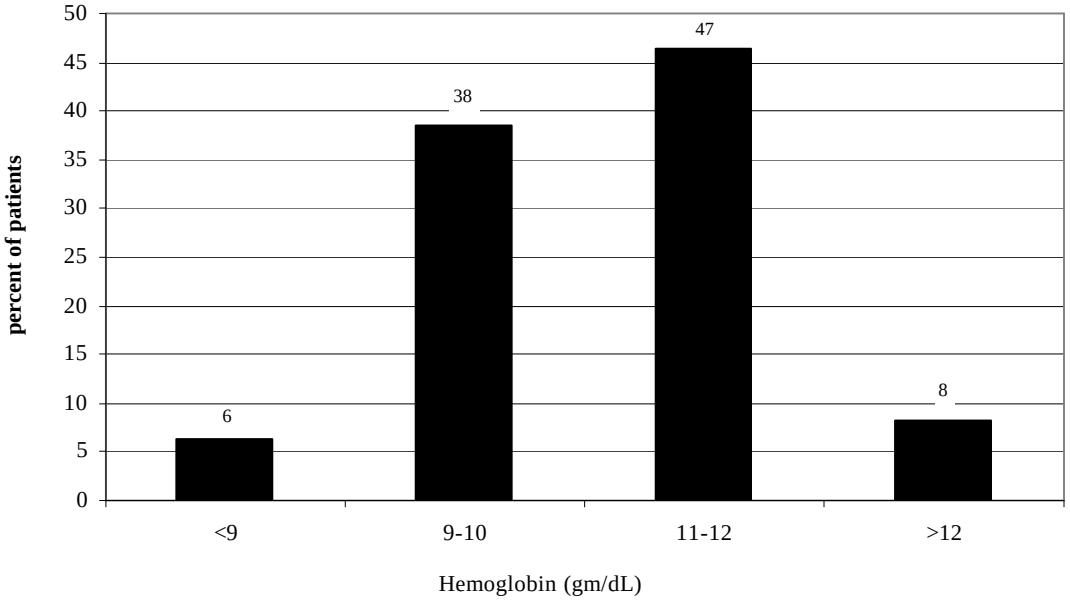


FIGURE 31: Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with mean hematocrit > 30%, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97, by race. 1998 ESRD Core Indicators Project.

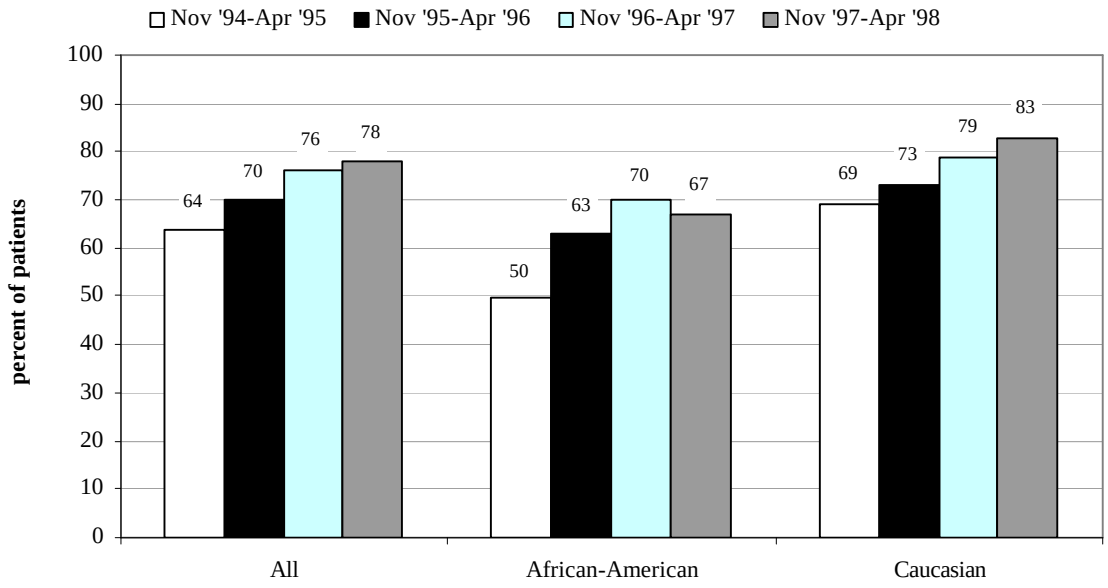


TABLE 15: Hematocrit values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '97-Apr '98, by patient characteristics. 1998 ESRD Core Indicators Project.

		Percent of patients with hematocrit values			
Patient Characteristic	Mean Hematocrit %	<28%	28-32%	33-36%	>36%
TOTAL	33.8	8	32	42	18
GENDER					
Men	34.3	6	28	44	22
Women	33.2	10	36	39	15
RACE					
American Indian/ Alaska Native	32.6	13	53	13	20
Asian/Pacific Islander	32.8	7	36	51	6
African-American	32.6	14	39	35	12
Caucasian	34.4	5	29	44	22
Other/Unknown	34.4	10	25	41	24
AGE GROUP (years)					
18-44	33.0	15	34	33	18
45-64	33.7	7	32	45	16
65+	34.6	3	31	44	22
DIAGNOSIS					
Diabetes Mellitus	34.0	4	34	44	18
Hypertension	33.6	10	32	39	19
Glomerulonephritis	33.4	10	32	39	19
Other/Unknown	33.9	10	29	42	19

Note: percents may not add up to 100% due to rounding

FIGURE 32a: Distribution of transferrin saturation values (%) for adult (aged ≥ 18 years) peritoneal dialysis patients, Nov '97-Apr '98 compared to Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

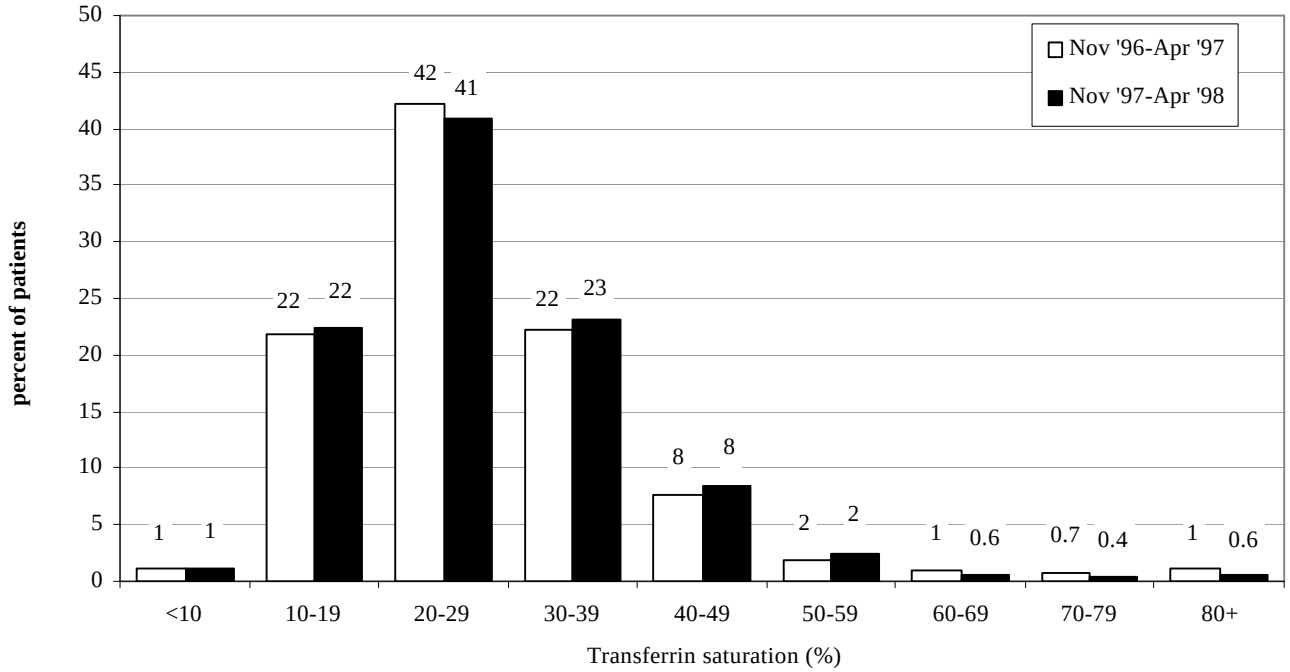
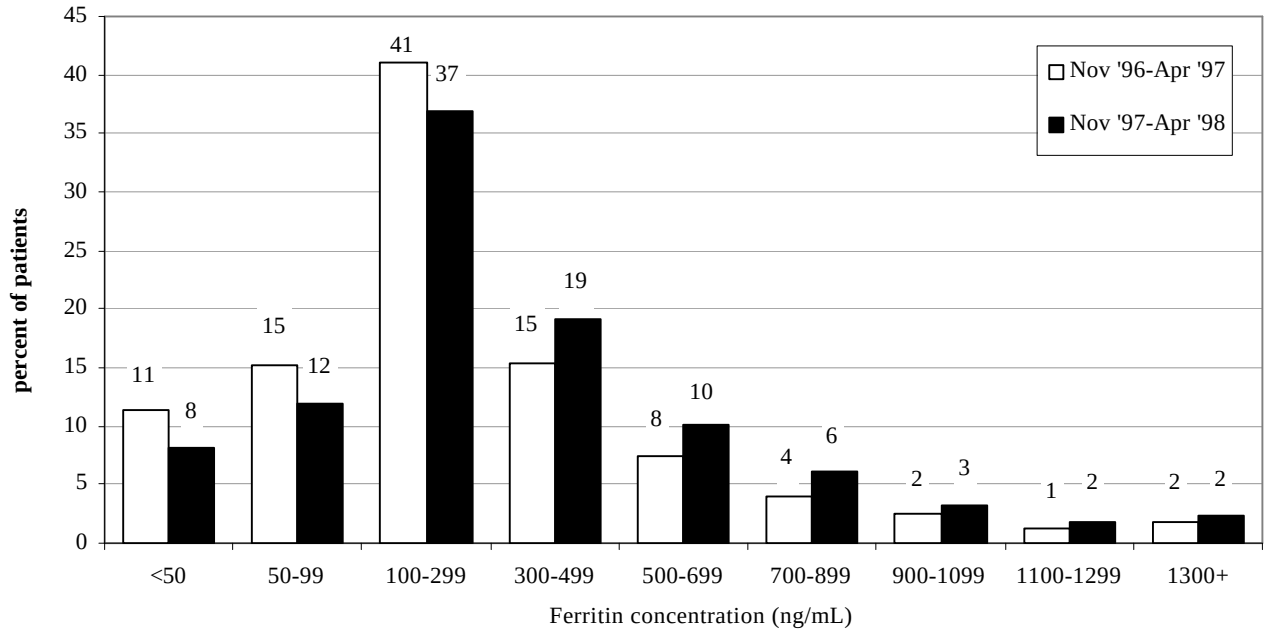


FIGURE 32b: Distribution of ferritin concentrations (ng/mL) for adult (aged ≥ 18 years) peritoneal dialysis patients, Nov '97-Apr '98 compared to Nov '96-Apr '97. 1998 ESRD Core Indicators Project.



The percent of adult (aged ≥ 18 years), peritoneal dialysis patients with severe anemia (hematocrit < 28%) remained essentially unchanged in the 1998 study period compared to the 1997 study period (FIGURE 33).

FIGURE 33. Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with severe anemia (hematocrit < 28%), by race, Nov '97-Apr '98 compared to Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

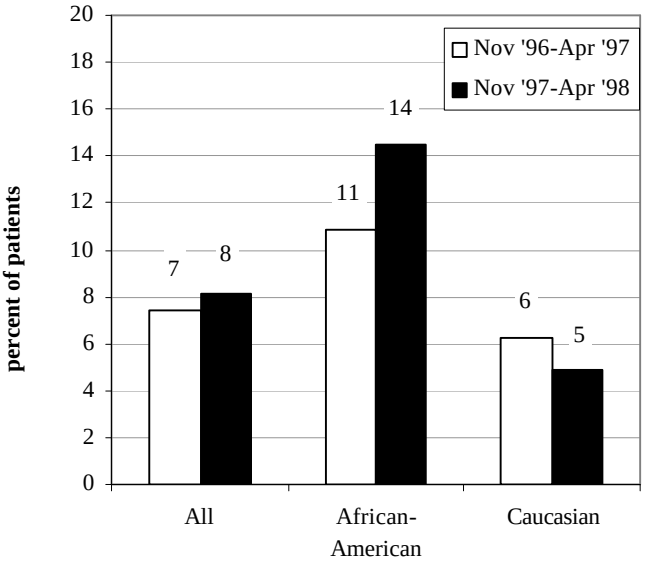
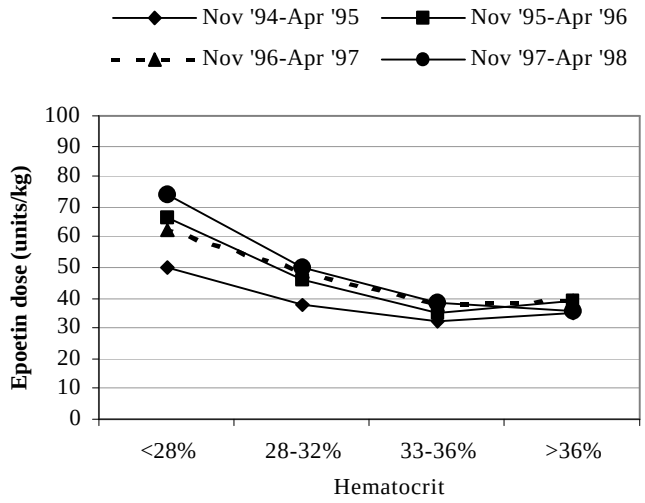


Figure 34 depicts a trend in Epoetin dosing from the 1995 study period to the 1998 study period, with an increasing mean Epoetin dose (units/kg) for patients receiving Epoetin in most hematocrit categories each successive study period.

FIGURE 34: Mean Epoetin dose (units/kg) by hematocrit category for adult (aged ≥ 18 years), peritoneal dialysis patients receiving Epoetin from Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.



D. SERUM ALBUMIN

1. November 1997-April 1998

The mean serum albumin value for patients whose value was determined by the BCG method (n=1138) was 3.5gm/dL and by the BCP method (n=227) was 3.3 gm/dL. The mean serum albumin value by gender, race, age, and diagnosis and the percent of patients with mean serum albumin values ≥ 3.5gm/dL by the BCG or ≥ 3.2gm/dL by the BCP method are shown in Table 16. The percent of patients with mean serum albumin values ≥ 3.5gm/dL by the BCG or ≥ 3.2gm/dL by the BCP method tended to be higher for men compared to women and for patients 18-44 years compared to older patients (TABLE 16).

2. November 1997-April 1998 compared to previous study years

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients with serum albumin values 3.5 gm/dL by the BCG or ≥ 3.2gm/dL by the BCP method from the 1995 study period to the 1998 study period.

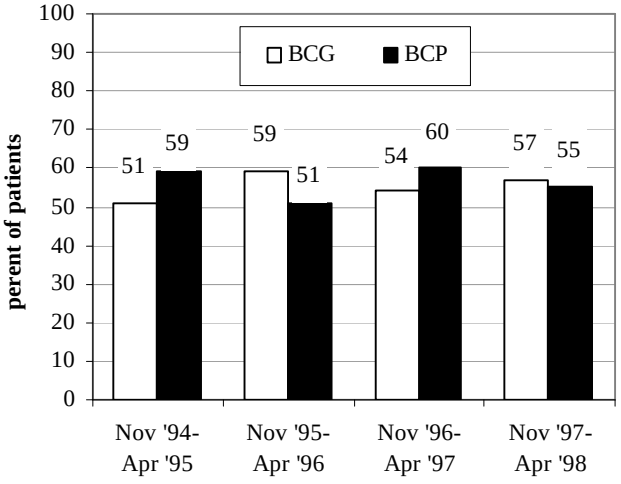
Figure 35 shows the percent of patients with mean serum albumin values ≥ 3.5gm/dL by the BCG or ≥ 3.2gm/dL by the BCP method during the 1998 study period compared to the 1995, 1996, and 1997 study periods.

TABLE 16: Mean serum albumin values (gm/dL) and percent of adult (aged ≥ 18 years) peritoneal dialysis patients with serum albumin values ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), Nov '97 - Apr '98, by patient characteristics and by laboratory method*. 1998 ESRD Core Indicators Project.

	BCG		BCP	
Patient Characteristic	Mean (gm/dL)	% ≥ 3.5 gm/dl	Mean (gm/dL)	% ≥ 3.2 gm/dL
TOTAL	3.5	57	3.3	55
GENDER				
Men	3.6	61	3.3	63
Women	3.5	53	3.2	48
RACE				
American Indian/Alaska Native	3.4	50	3.3	40
Asian/Pacific Islander	3.8	72	3.2	53
African-American	3.5	56	3.2	49
Caucasian	3.5	57	3.3	57
Other/Unknown	3.6	62	3.4	69
AGE GROUP (years)				
18-44	3.7	68	3.3	64
45-64	3.5	57	3.3	59
65+	3.4	48	3.2	44
DIAGNOSIS				
Diabetes Mellitus	3.4	51	3.1	47
Hypertension	3.5	57	3.3	54
Glomerulonephritis	3.7	69	3.3	60
Other/Unknown	3.6	60	3.3	60

*Laboratory Methods: BCG = bromcresol green; BCP = bromcresol purple

FIGURE 35: Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.



E. BLOOD PRESSURE CONTROL

1. November 1997-April 1998

The mean systolic and diastolic blood pressure values for adult peritoneal dialysis patients during this study period were 136 mmHg and 79 mmHg, respectively.

The percent of these patients with a mean systolic blood pressure > 150 mmHg or diastolic blood pressure > 90 mmHg, which may be a measure for inadequately controlled hypertension, by gender, race, age group and diagnosis, is shown in Table 17. The overall prevalence of inadequately controlled hypertension (by the diastolic measure) was 16%; this prevalence was significantly higher for African-Americans compared to Caucasians, patients 18-44 years old compared to older patients, and for non-diabetics compared to diabetics (TABLE 17).

TABLE 17: Mean blood pressure (BP) values and percent of adult (aged ≥ 18 years) peritoneal dialysis patients with systolic BP > 150 mmHg or diastolic BP > 90 mmHg, Nov '97-Apr '98, by patient characteristics.
1998 ESRD Core Indicators Project.

Patient Characteristic	Systolic BP (mmHg)		Diastolic BP (mmHg)	
	Mean	% > 150	Mean	% > 90
TOTAL	136	23	79	16
GENDER				
Male	136	22	80	17
Female	137	24	79	16
RACE				
American Indian/ Alaska Native	139	27	84	40
Asian/Pacific Islander	135	17	80	18
African-American	141	31	83	27
Caucasian	135	20	77	11
Other/Unknown	135	22	79	19
AGE GROUP (yrs)				
18-44	136	20	86	32
45-64	138	28	80	15
65+	135	19	73	4
DIAGNOSIS				
Diabetes Mellitus	140	29	77	8
Hypertension	136	24	80	20
Glomerulonephritis	136	19	82	24
Other/Unknown	132	17	80	21

2. November 1997-April 1998 compared to previous study years

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients with hypertension or by JNC6 category over the four study periods (FIGURES 36, 37).

FIGURE 36: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean blood pressure values > 150 (systolic) or > 90 (diastolic) mmHg, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96 and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.

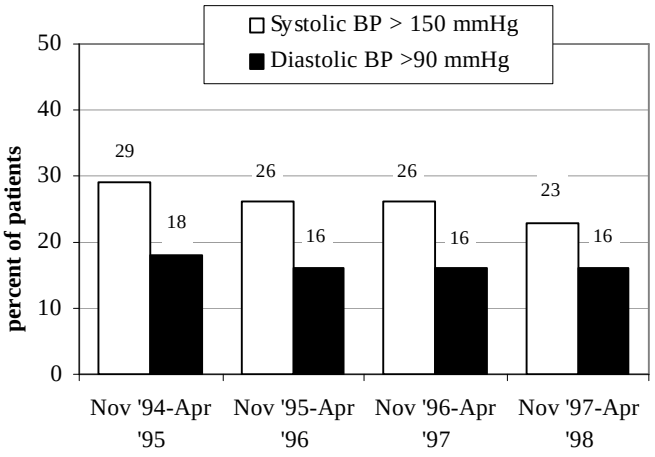
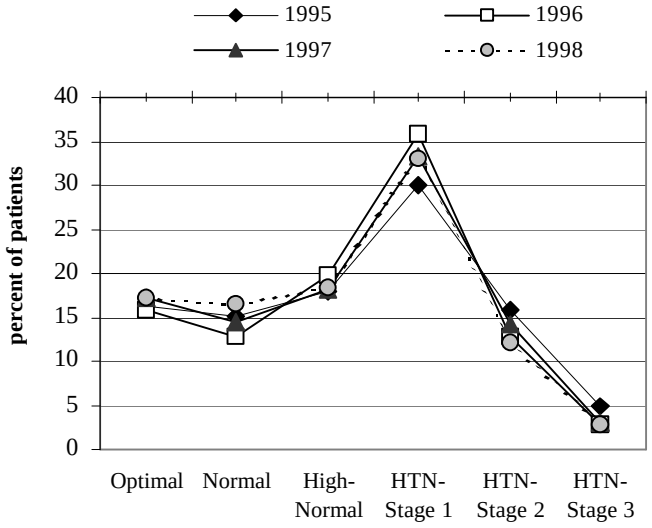


FIGURE 37: Distribution of blood pressure values by JNC6 Category for adult (aged ≥ 18 years) peritoneal dialysis patients, Nov '97-Apr '98 compared to Nov '94-Apr '95, Nov '95-Apr '96, and Nov '96-Apr '97. 1998 ESRD Core Indicators Project.



1999 Data Collection Effort

In 1999, we will again collect data for these ESRD Core Indicators on a national sample of adult in-center hemodialysis and peritoneal dialysis patients. Any questions about the Project can be addressed to your ESRD Network staff or to members of the ESRD Core Indicators Workgroup (Appendices 1 & 2).

VIII. IMPORTANT NOTE

The data in this report are intended to stimulate the development of quality improvement (QI) projects in dialysis facilities. The data collected for this project were necessarily limited: not all dialytic parameters that influence patient care for these clinical measures were collected. In addition, the project did not attempt to develop facility specific profiles of care.

During 1999, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD Core Indicators Project as well as other data from which we can derive information about the patients in the sample identified for this project.

As you review these data, ask yourself questions about how your patients' clinical characteristics compare to these national hemodialysis and peritoneal dialysis patient profiles and Network hemodialysis patient profiles. Additional information must be collected at your facility if you wish to answer these questions and develop ways to improve patient care for your patients. Your ESRD Network staff and Medical Review Board members are available to assist you in using these data in your QI activities and in developing facility specific QI projects.

IX. APPENDICES

Appendix 1. 1998 ESRD Core Indicators Workgroup Members:

Evelyn Butera, MS, RN, CNN
American Nephrology Nurses' Association
Satellite Dialysis Centers, Inc,
345 Convention Way, Suite B
Redwood City, CA 94063-1402

Diane Frankenfield, DrPH
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd
Baltimore, MD 21244

Pamela Frederick, MSB
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd
Baltimore, MD 21244

Kay Hall, BSN, RN, CNN
Health Care Financing Administration
CSQ, ROVI
1301 Young St., Rm 714
Dallas, TX 75202

Curtis Johnson, Pharm D
Professor School of Pharmacy
University of Wisconsin
425 North Charter Street
Madison, WI 53706

Linda Moore, RD
SangStat Medical Corp
7144 Donnington Dr
Germantown, TN 38138

William F. Owen, Jr. MD
Renal Physicians Association
Dialysis, ASB1-2nd Floor,
Brigham & Women's Hospital
75 Francis St.
Boston, MA 02115

Susan Raulie, RN
National Renal Administrators Association
Bay Area Dialysis Services
1125 Third Street
Corpus Christi, TX 78404

Michael Rocco, MD, MS
Wake Forest University School of Medicine
Section of Nephrology
Medical Center Blvd
Winston-Salem NC 27157-1053

Susan Stark
Forum of ESRD Networks
ESRD Network 9 & 10
911 East 86th St, Suite 202
Indianapolis, IN 46240

Lisa Taylor, RN
Forum of ESRD Networks
ESRD Network 12
Northpointe Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153

Jay Wish, MD
Forum of ESRD Networks
University Hospital of Cleveland
Division of Nephrology
Rm 8124, Lakeside Bldg
2074 Abington Rd
Cleveland, OH 44106

Appendix 1. 1998 ESRD Core Indicators Workgroup - Peritoneal Dialysis Subcommittee Members:

George Bailie, Pharm D, Ph.D.
Professor, Dept of Pharmacy Practice
Albany College of Pharmacy
106 New Scotland Avenue
Albany, NY 12208-3492

Michael Flanigan, MD
Assistant Professor
Univ of Iowa Hosp & Clinic
Dept of Nephrology
Newton Road
Iowa City, IA 52242

Diane Frankenfield, DrPH
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd
Baltimore, MD 21244

Pamela Frederick, MSB
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd
Baltimore, MD 21244

Kay Hall, BSN, RN, CNN
Health Care Financing Administration
CSQ, ROVI
1301 Young St., Rm 714
Dallas, TX 75202

William McClellan, MD
Clark Holder Clinic
303 Smith Street
LaGrange, GA 30240

Barbara Prowant, MSN, RN
Univ of Missouri-Columbia School of Medicine
Dialysis Clinic Inc
3300 Lemone Blvd
Columbia MO 65201

Michael Rocco, MD, MS
Wake Forest University School of Medicine
Section of Nephrology
Medical Center Blvd
Winston-Salem NC 27157-1053

Lisa Taylor, RN
ESRD Network 12
Northpointe Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153

Appendix 2. HCFA OFFICES AND ESRD NETWORKS

HCFA Offices

Office of Clinical Standards and Quality
Quality Measurement and Health Assessment Group
S3-02-01
7500 Security Boulevard
Baltimore, MD 21244
(410) 786-5785

Health Care Financing Administration - Region I
Division of Clinical Standards and Quality,
Clinical Standards Branch
Room 2275
JFK Federal Building
Boston, MA 02203-0003
(617) 565-3136

Health Care Financing Administration - Region VII
Division of Clinical Standards and Quality,
Medical Review Branch
Richard Bolling Federal Building
60l East l2th Street, Room 242
Kansas City, MO 64106-2808
(816) 426-5746

Health Care Financing Administration - Region VI
Division of Clinical Standards and Quality
Room 714
1301 Young St
Dallas, TX 75202
(214) 767-4405

Health Care Financing Administration - Region X
Division of Clinical Standards and Quality,
2201 Sixth Avenue, Mail Stop (RX-42)
Seattle, WA 98121-2500
(206) 615-2317

ESRD Networks

ESRD Network Organization No. 1
ESRD Network of New England
P.O. Box 9484
New Haven, CT 06534
Region I: ME, NH,VT, MA, CT, RI
(203) 387-9332

ESRD Network Organization No. 2
1216 Fifth Ave
New York, NY 10029
Region I: NY
(212) 289-4524

ESRD Network Organization No. 3
Cranbury Plaza
2525 Route 130 - Bldg C
Cranbury, NJ 08512-9595
Region I: NJ, PR, VI
(908) 395-5544

ESRD Network Organization No. 4
University of Pittsburgh Medical Center
200 Lothrop St.
Pittsburgh, PA 15213-2582
Region I: PA, DE
(412) 647-3428

ESRD Network Organization No. 5
Mid-Atlantic Renal Coalition
1527 Huguenot Road
Midlothian, VA 23113
Region I: DC, MD, VA, WV
(804) 794-3757

ESRD Network Organization No. 6
Lake Plaza East
900 Ridgefield Dr., Suite 220
Raleigh, NC 27609
Region VI: GA, NC, SC
(919) 876-7545

Appendix 2 - HCFA Offices and ESRD Networks

ESRD Network Organization No. 7
ESRD Network of Florida, Inc.
1 Davis Boulevard, Suite 304
Tampa, FL 33606
Region VI: FL
(813) 251-8686

ESRD Network Organization No. 8
Network Eight, Inc.
P.O. Box 55868
Jackson, MS 39296-5668
Region VI: AL, MS, TN
(601) 936-9260

ESRD Network Organization No. 9 & 10
The Renal Network
911 East 86th Street, Suite 202
Indianapolis, IN 46240-1858
Region VII: KY, IN, OH, IL
(317) 257-8265

ESRD Network Organization No. 11
ESRD Renal Network
of the Upper Mid-West, Inc.
970 Raymond Avenue, Suite 205
St. Paul, MN 55114
Region VII: MI, MN, WI, ND, SD
(651) 644-9877

ESRD Network Organization No. 12
Northpoint Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153
Region VII: MO, IA, NE, KS
(816) 880-9990

ESRD Network Organization No. 13
6600 N Meridan Ave, Ste 155
Oklahoma City, OK 73116-1421
Region VI: AR, LA, OK
(405) 843-8688

ESRD Network Organization No. 14
ESRD Network of Texas, Inc.
14114 Dallas Parkway, # 660
Dallas, TX 75240
Region VI: TX
(972) 503-3215

ESRD Network Organization No. 15
Intermountain ESRD Network, Inc.
1301 Pennsylvania Street, Suite 220
Denver, CO 80203-5012
Region X: NM, CO, WY, UT, AZ, NV
(303) 831-8818

ESRD Network Organization No. 16
Northwest Renal Network
4702 42nd Ave, SW
Seattle, WA 98116
Region X: MT, AK, ID, OR, WA
(206) 448-1803

ESRD Network Organization No. 17
TransPacific Renal Network
25 Mitchell Blvd
Suite 7
San Rafael, CA 94903
Region X: No. CA, HI, Mariana Isl., GU, AS
(415) 472-8590

ESRD Network Organization No. 18
Southern California Renal Disease Council
6255 Sunset Boulevard, Suite 2211
Los Angeles, CA 90028
Region X: So. CA
(323) 962-2020

IN-CENTER HEMODIALYSIS (HD) CORE INDICATORS DATA COLLECTION FORM: 1998

BEFORE COMPLETING FORM, READ INSTRUCTIONS ON BACK OF FORM

PATIENT IDENTIFICATION

MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW

10.a Is patient Hispanic? _____ Yes _____ No _____ Unknown

11. **IS THE ABOVE PATIENT INFORMATION CORRECT - Please verify race and check question 10 a. above.** ___ YES; Go to question 12.

___ NO; Make corrections above, then go to question 12. ___ UNKNOWN; STOP. Note the provider if known & return form to Network.

12. Patient's height: _____ inches or _____ centimeters.

LAB DATA. The following data are requested for OCT, NOV and DEC, 1997. For each question, use the **FIRST** LAB VALUES OF THE MONTH. Do not leave any questions blank. **Enter the following codes in the spaces below if lab values cannot be found**: **NF** if Not Found, **HOSP** if hospitalized during the entire month, **TRANS** if absent during the entire month, **NP** if tests not performed at any time during the month.

	OCT 1997	NOV 1997	DEC 1997
13. **ANEMIA MANAGEMENT**: **Enter the FIRST monthly HCT AND HGB determined by the LABORATORY for EACH MONTH: OCT, NOV, DEC 1997. DO NOT ENTER SPUN HCT VALUE unless your facility does not obtain lab hcts. Also enter the prescribed WEEKLY EPO dose and the route of administration; the first monthly Ferritin and Percent Transferrin Saturation value and the route of iron administration.**			
A. First monthly pre-dialysis laboratory hematocrit:	____ ____ . ____ %	____ ____ . ____ %	____ ____ . ____ %
B. First monthly pre dialysis laboratory hemoglobin:	____ ____ . ____ gm	____ ____ . ____ gm	____ ____ . ____ gm
C. Was a prescription for EPO in effect (EVEN IF patient did not receive dose) during the WEEK the monthly hct above was drawn?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
D. If yes, what was the **PRESCRIBED WEEKLY EPO** dose at the time immediately before the above HCT was drawn?	_____ **units/wk**	_____ **units/wk**	_____ **units/wk**
E. What was the prescribed route of EPO administration?	____ IV ____ SC	____ IV ____ SC	____ IV ____ SC
F. First monthly Ferritin value.	_____ ng/mL	_____ ng/mL	_____ ng/mL
G. First monthly **Transferrin Saturation %** value (see instructions).	_____ %	_____ %	_____ %
H. Was a prescription for Iron in effect during the month?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
I. If yes, what was the route of iron administration? (check all that apply)	____ IV ____ P.O.	____ IV ____ P.O.	____ IV ____ P.O.
14. **DIALYSIS ADEQUACY ASSESSMENT**: **Enter the first monthly pre and post dialysis BUN FOR EACH MONTH: OCT, NOV, DEC 1997. The pre- and post-dialysis BUNs must be drawn on the same day of the month. If only performed quarterly, enter the FIRST values for month performed and enter "NP" for the other two months. Also, enter the patient's actual DELIVERED time on dialysis when the BUNs were drawn and the CODE for the name of the dialyzer used at the time the BUNs were drawn. (See attached chart for the dialyzer codes.)**			
A. First monthly Pre dialysis BUN:	____ ____ ____mg/dl	____ ____ ____mg/dl	____ ____ ____mg/dl
B. First monthly Post dialysis BUN:	____ ____ ____mg/dl	____ ____ ____mg/dl	____ ____ ____mg/dl
C. Patient's **PRE & POST** dialysis weight when BUNs above drawn: (Circle either lbs or kgs)	Pre: _____lbs/kgs Post: _____ lbs/kgs	Pre: _____lbs/kgs Post: _____ lbs/kgs	Pre: _____lbs/kgs Post: _____ lbs/kgs
D. Actual **DELIVERED** time on dialysis at session when BUNs drawn:	____hrs ____ ____min	____hrs ____ ____min	____hrs ____ ____min
E. Code for dialyzer used at session when BUNs drawn (see chart):	_____	_____	_____
15. **SERUM ALBUMIN**: **Enter the FIRST monthly serum albumin FOR EACH MONTH: OCT, NOV, DEC 1997. Check the method used by lab to determine the serum albumins. If method unknown, please call lab to find out. Do not leave blank.**			
A. First monthly serum albumin:	_____ . _____ gm/dl	_____ . _____ gm/dl	_____ . _____ gm/dl
B. Check lab method used (BCG=bromcresol green; BCP=bromcresol purple):	_____ BCGreen _____ BCPurple	_____ BCGreen _____ BCPurple	_____ BCGreen _____ BCPurple

16. Name, title and phone number of individual completing form:

INSTRUCTIONS FOR COMPLETING THE IN-CENTER HD CORE INDICATORS DATA COLLECTION FORM - 1998

If the information is incorrect, make corrections to the right of the label. The label on the top left side of the form (#'s 1-8) contains the following patient identifying information.

1. LAST and first name.
2. DATE of birth (DOB) as MM/DD/YYYY.
3. SOCIAL Security Number (SSN).
4. HEALTH Insurance Claim Number (HIC).
5. SEX (M or 1=Male; F or 2=Female).
6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander; 6=American Indian/Alaskan Native.
7. PRIMARY cause of renal failure by HCFA-2728 code.
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
9. ESRD Network number: Do not make corrections to this item. **10.** Facility's Medicare provider number.
10a. Is patient Hispanic? Please check either Yes, No, or Unknown, as appropriate.
11. Review the patient and facility specific information contained on the pre-printed label (Please verify the patient's race, question no. 6 above, and check question 10 a.) and mark either Yes, No or Unknown. If No is marked, write corrections to the pre-printed information in the space to the right of the label. If Unknown is marked, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on December 31, 1997, if known.

To answer questions 12 - 15, review the patient's medical record for the months of October through December 1997. Do not leave any items blank. Enter the following codes if the information cannot be located: "**NF**" if not found, "**HOSP**" if hospitalized during the entire month, "**TRANS**" if absent during the entire month, "**NP**" if test not performed at any time during the month.

12. Enter the patient's height in inches or centimeters. You may ask the patient his/her height to obtain this information.

13 A. Enter the patient's FIRST MONTHLY pre-dialysis hematocrit (HCT) value determined by the laboratory's Coulter Counter or other hematology instrument for EACH month - October, November and December 1997. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.

13.B. Enter the patient's FIRST MONTHLY pre-dialysis hemoglobin (HGB) value determined by the lab's Coulter Counter or other hematology instrument for EACH month - Oct, Nov, and Dec, 1997.

13C. Check the appropriate space to indicate if there was a prescription for EPO in effect during the WEEK the monthly HCT was drawn, even if the patient did not receive the EPO dose.

13D. If the answer to 13C is yes, please enter the PRESCRIBED WEEKLY EPO dose at the time immediately before the monthly HCT was drawn. If prescribed less frequently than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using a sliding scale for EPO dosing or giving EPO at each treatment, total all the doses given during the week and enter this value.

13E. Check the appropriate space to indicate the route of administration for EPO (intravenously (IV) or subcutaneous (SC)).

13F. Enter the patient's FIRST MONTHLY ferritin value recorded EACH month for Oct, Nov, and Dec, 1997. If a Ferritin test is not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).

13G. Enter the patient's FIRST MONTHLY transferrin saturation value recorded EACH month for Oct, Nov and Dec 1997. If an transferrin saturation test is not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).

13H. Check either Yes or No to indicate if there was a prescription for Iron in effect at any time during each month of Oct, Nov, and Dec,1997.

13I. If the answer to 13H. is yes, please check the appropriate space to indicate the route of iron administration (intravenously (IV) or by mouth (P.O.)) each month. If patient received iron by mouth and IV, check both spaces.

14A,B. Enter the patient's FIRST pre and post dialysis BUN values recorded EACH month for Oct, Nov and Dec,1997. The BUN values must be drawn on the same day. If pre and post dialysis BUNs are only performed quarterly, enter the values for the month when performed and record "not performed" for the other two months.

14C. Enter the patient's PRE & POST dialysis weight at the session when the pre and post dialysis BUN levels were drawn; circle either lbs or kgs as appropriate.

14D. Enter the patient's ACTUAL DELIVERED time on dialysis during the session when the BUN levels were drawn. DO NOT ENTER THE PRESCRIBED TIME ON DIALYSIS.

14E. Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used on the day the blood samples were drawn for the pre and post dialysis BUNs in October, November and December 1997. If the dialyzer used is not on the chart, enter the code for other (9999).

15A. Enter the patient's FIRST serum albumin value recorded EACH month for October, November and December 1997.

15B. Check the appropriate method used by the laboratory to determine the serum albumin levels (bromcresol green or bromcresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.

16. Enter the name, title and phone number of the person who completed the form. Forward the completed form to your ESRD Network office.

PERITONEAL DIALYSIS CORE INDICATORS DATA COLLECTION FORM: 1998

BEFORE COMPLETING FORM, PLEASE READ INSTRUCTIONS ON PAGES 3 & 4

PATIENT IDENTIFICATION

MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW

10.a Is patient Hispanic? _____ Yes, _____ No _____ Unknown

11. If the above patient information is incorrect, make corrections in space above, then continue to question 12. Please verify the patient's race and check question 10 a. above. If patient unknown or was not dialyzed in the unit at any time during Nov - Dec 1997 & Jan - Apr 1998, return the form to the Network.

12. **Patient's height (MUST COMPLETE**): _____ inches _____ centimeters 13. **Does patient have limb amputation(s**): _____ Yes _____ No

LAB DATA. The following data are requested for the 2-MONTH TIME PERIODS NOV-DEC 1997, JAN-FEB 1998, & MAR-APR 1998. For each question, where appropriate use the **1st** Lab values obtained during each of the 2-Month Time Periods. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED **NF** if Not Found, **HOSP** if Hospitalized during the entire time period; **TRANS** if absent during the entire time period, **NP** if tests Not Performed at any time during the time period.

	NOV - DEC 1997	JAN - FEB 1998	MAR - APR 1998
14. **ADEQUACY:** Enter the 1ST monthly adequacy measurements/results listed below that were obtained FOR EACH 2-MONTH time period: NOV-DEC 1997, JAN - FEB 1998, MAR-APR 1998. ONLY enter those tests performed. **Please read instructions on pages 3 & 4 before completing this section**.			
A. Check all the dialysis modality(s) the patient was on during each 2-month time period:	____ CAPD; ____ Cycler ____ HEMO; ____ Tidal	____ CAPD; ____ Cycler; ____ HEMO; ____ Tidal	____ CAPD; ____ Cycler; ____ HEMO; ____ Tidal
B. Patient weight at 1st adequacy assessment for 2-month time period: (Circle either lbs or kgs)	_____ lbs kgs	_____ lbs kgs	_____ lbs kgs
C. Patient's dialysis modality when adequacy measures below were performed.	____ CAPD; ____ Cycler ____ Tidal	____ CAPD; ____ Cycler; ____ Tidal	____ CAPD; ____ Cycler, ____ Tidal
D. 1st 24 hr DIALYSATE outflow volume for 2-month time period:	_____ ml	_____ ml	_____ ml
E. 1st 24 hr DIALYSATE **urea nitrogen** for 2-month time period:	____ ____ ____mg/dl	____ ____ ____mg/dl	____ ____ ____mg/dl
F. 1st 24 hr DIALYSATE **creatinine** for 2-month time period:	____ ____ . ____mg/dl	____ ____ . ____mg/dl	____ ____ . ____mg/dl
G. 1st 24 hr URINE volume for 2-month time period: (If 24 hr urine was not collected check NP. If patient is anuric, check anuric and go to question 14. J.)	_____ ml ____ NP ____ anuric	_____ ml ____ NP ____ anuric	_____ ml ____ NP ____ anuric
H. 1st 24 hr URINE **urea nitrogen** for 2-month time period:	____ ____ ____mg/dl	____ ____ ____mg/dl	____ ____ ____mg/dl
I. 1st 24 hr URINE **creatinine** for 2-month time period:	____ ____ . ____mg/dl	____ ____ . ____mg/dl	____ ____ . ____mg/dl
J. SERUM BUN at 1st adequacy assessment for 2-month time period:	____ ____ ____mg/dl	____ ____ ____mg/dl	____ ____ ____mg/dl
K. SERUM creatinine at 1st adequacy assessment for 2-month period:	____ ____ . ____ mg/dl	____ ____ . ____ mg/dl	____ . ____ mg/dl
L. 1st weekly Kt/V urea for each 2-month time period:	____ . ____ ____	____ . ____ ____	____ . ____ ____
M. Method by which V above was calculated (check one): (See instructions on page 4)	____ %BW ____ Hume ____ Watson ____ Other	____ %BW ____ Hume ____ Watson ____ Other	____ %BW ____ Hume ____ Watson ____ Other
N. 1st weekly creatinine clearance for each 2-month time period:	_____ L/wk	_____ L/wk	_____ L/wk
O. Is creatinine clearance corrected for body surface area?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No

PERITONEAL DIALYSIS CORE INDICATORS DATA COLLECTION FORM: 1998 CONTINUED

	NOV - DEC 1997	JAN - FEB 1998	MAR - APR 1998
15. PERITONEAL DIALYSIS PRESCRIPTION: For the following questions - record the PD prescription in effect at the time the adequacy measures/results recorded in Q. 14 were performed. If adequacy measures/results were not performed in each 2-month time period, record the first PD prescription found in the medical record for each 2-month time period. Complete all items that are applicable. Please read instructions on page 4 before completing this section. One PD prescription category MUST be completed for each 2-month time period, unless the patient was on HD the entire 2-month time period.			
CAPD PRESCRIPTION: A. Prescribed inflow volume for a SINGLE exchange:	_____ ml	_____ ml	_____ ml
B. Prescribed number of exchanges per 24 hrs:	_____	_____	_____
CYCLER NIGHT TIME PRESCRIPTION: C. Prescribed inflow volume for a SINGLE exchange:	_____ ml	_____ ml	_____ ml
D. Prescribed number of nighttime exchanges per 24 hrs:	_____	_____	_____
E. Prescribed dwell time for a SINGLE exchange (average time if varied):	_____ min	_____ min	_____ min
CYCLER DAY TIME PRESCRIPTION: F. Prescribed inflow volume for a SINGLE exchange:	_____ ml	_____ ml	_____ ml
G. Prescribed number of daytime exchanges per 24 hrs:	_____	_____	_____
H. Prescribed dwell time for a SINGLE exchange (average time if varied):	_____ min	_____ min	_____ min
16. Four Hour Peritoneal Equilibration Test (PET): Enter in this section only the calculated 4 hr dialysate to plasma creatinine(D/P) ratio. Refer to records in the patient's medical chart outside the 6-month time frame, if necessary, to respond to the following question.			
A. Most recent four hour PET test result for D/P creatinine: _____ . _____ _____ Date of this test result: _____/_____/_____			
LAB DATA. The following data are requested for the 2-MONTH TIME PERIODS NOV-DEC 1997, JAN-FEB 1998, & MAR-APR 1998. For each question, where appropriate use the **1st** Lab values obtained during each of the 2-Month Time Periods. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: **NF** if Not Found, **HOSP** if Hospitalized during the entire time period, **TRANS** if absent during the entire time period, **NP** if tests Not Performed at time during the time period.			
	NOV - DEC 1997	**JAN - FEB 1998**	**MAR - APR 1998**
17. **ANEMIA MANAGEMENT**: Enter the FIRST HCT and HGB determined by lab's Coulter Counter or other hematology instrument FOR EACH 2-MONTH time period: NOV-DEC 1997, JAN-FEB 1998, MAR-APR 1998. DO NOT ENTER SPUN HCT VALUE, unless your facility does not obtain lab hcts.			
A. 1st laboratory hematocrit obtained for 2-month time period:	____ ____ . ____ %	____ ____ . ____ %	____ ____ . ____ %
B. 1st laboratory hemoglobin obtained for 2-month time period:	____ ____ . ____ gm	____ ____ . ____ gm	____ ____ . ____ gm
C. Was a prescription for EPO in effect (**EVEN IF** patient did not receive dose) during the week the monthly hct above was drawn?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
D. If yes, what was the **PRESCRIBED WEEKLY** EPO dose at the time immediately before the above HCT was drawn?	_____ **units/wk**	_____ **units/wk**	_____ **units/wk**
E. First **Transferrin Saturation %** value obtained for 2-month time period (see instructions).	_____ %	_____ %	_____ %
F. First Ferritin value obtained for 2-month time period.	_____ ng/mL	_____ ng/mL	_____ ng/mL
G. Was a prescription for Iron in effect during the 2-month time period?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
H. If yes, what was the route of administration? (check all that apply)	_____ IV _____ P.O.	_____ IV _____ P.O.	_____ IV _____ P.O.
18. SERUM ALBUMIN: Enter the 1ST serum albumin obtained FOR EACH 2-MONTH time period: NOV-DEC 1997, JAN-FEB 1998, MAR-APR 1998. Check the method used by lab to determine the serum albumins. If method unknown, please call lab to find out. Do not leave blank.			
A. 1st serum albumin obtained for 2-month time period:	_____ . _____ gm/dl	_____ . _____ gm/dl	_____ . _____ gm/dl
B. Check lab method used (BCG=bromcresol green; BCP=bromcresol purple):	_____ BCGreen _____ BCPurple	_____ BCGreen _____ BCPurple	_____ BCGreen _____ BCPurple
19. **BLOOD PRESSURE**: Enter the 1ST monthly upright BP (systolic/diastolic) FOR **EACH** 2-MONTH time period: NOV-DEC 1997, JAN-FEB 1998, MAR- APR 1998. If the SBP or the DBP was unobtainable, enter UNOB or P for palpated or D for Doppler in appropriate space.			

INSTRUCTIONS FOR COMPLETING THE PERITONEAL DIALYSIS CORE INDICATORS DATA COLLECTION FORM - 1998

The label on the top left side of the form (#'s 1-8) contains the following patient identifying information. If the information is incorrect, make corrections to the right of the label.

1. LAST and first name.
2. DATE of birth (DOB) as MM/DD/YYYY.
3. SOCIAL Security Number (SSN).
4. HEALTH Insurance Claim Number (HIC).
5. SEX (M or 1=Male; F or 2=Female).
6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander; 6=American Indian/Alaskan Native.)
7. PRIMARY cause of renal failure by HCFA-2728 code.
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
9. ESRD Network number: Do not make corrections to this item.
10. Facility's Medicare provider number.

10a. Is the patient Hispanic? Check either Yes, No, or Unknown, as appropriate.

11. Review the patient and facility specific information contained on the pre-printed label. Please verify the patient's race, question no. 6 above, and check question 10a. If any of the information is incorrect, write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during Nov - Dec 1997 & Jan - Apr 1998, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on April 30, 1998, if known.

To answer questions 12 - 19, review the patient's clinic or facility medical record for each two month time period: NOV-DEC 1997; JAN-FEB 1998; & MAR-APR 1998. Do not leave any items blank. Enter the following codes if the information cannot be located: **NF** if not found, **HOSP** if hospitalized during the entire time period, **TRANS** if absent during the entire time period, **NP** if tests not performed at any time during the time period. For question 16, you may need to refer to information in the patient's medical record that is outside this six month time period.

12. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank, you may ask the patient his/her height to obtain this information. If patient had both legs amputated, record pre-amputation height and check YES for question no. 13.

13. Check either YES or NO if the patient had arm or leg amputation (s).

14. Enter the FIRST dialysis adequacy measurements that were obtained for each 2 month time period. YOU MAY NOT HAVE DATA ON THESE TESTS FOR EACH 2-MONTH TIME PERIOD. If the adequacy measurements were only performed quarterly or each 6-months, enter the first adequacy measurements for each 2-month period and enter "NP" (for not performed) for any other 2-month interval. IF THE PATIENT WAS ON HEMODIALYSIS DURING THE ENTIRE 2-MONTH TIME PERIOD MARK QUESTIONS 14. B-O, HEMO.

14. A. Check the modality the patient was on during each 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. CHECK either CAPD, Cycler, HEMO or Tidal. If the patient was on more than one modality during the 2-month time period, check all applicable modalities. Tidal patients are Cycler patients for which the dialysate is partial drained between some exchanges. (see definitions under number 15)

14. B. Enter the patient's weight at the clinic/facility visit when the adequacy measurements were obtained, circle lbs or kgs as appropriate.

14.C. Check the modality the patient was on during each 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998 when the adequacy measures in questions 14 D - N were performed. If adequacy measures were not performed during the 2-month time period, enter NP and skip questions 14 D - O.

14. D, E & F Enter the 24 hr DIALYSATE outflow volume, urea nitrogen and creatinine obtained for the **FIRST** adequacy assessment for each 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. If a 24 hr dialysate outflow volume, urea nitrogen and creatinine were NOT measured at any time during each of these 2-month time periods, enter NP (for not performed) in the appropriate 2-month time period spaces. ONLY ENTER ACTUAL MEASURED 24 HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. Please report the dialysate outflow or drain volume NOT the prescribed volume.

14. G, H. & I. Enter the 24 hr URINE volume, urea nitrogen and creatinine obtained for the **FIRST** adequacy assessment for each 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. ONLY ENTER ACTUAL MEASURED 24 HR URINE VOLUME - DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24 hr urine volume was not measured check **NP** for not performed OR if the patient is anuric, check anuric. If NP or anuric is checked, SKIP TO QUESTION 14. J. If urine urea nitrogen and creatinine were only measured quarterly or each 6-months, enter the FIRST value obtained for each 2-month time period and enter **NP** for any 2-month time period when not performed.

14. J. & K Enter the SERUM BUN and SERUM CREATININE obtained at **FIRST** adequacy assessment for each 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. If adequacy assessment measurements are only obtained quarterly or each 6-months, enter serum BUN and creatinine results for the corresponding dialysate data in 14 D-F and enter NP in the appropriate spaces for any 2-month time period when not performed.

14. L. & N. Enter the FIRST WEEKLY Kt/V UREA and/or WEEKLY CREATININE CLEARANCE for each 2 month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. NOTE: If you have a value for weekly Kt/V urea (or creatinine clearance) for a particular two month period, please complete the corresponding values for questions 14 D-K for 24 hour dialysate volume, 24 hour dialysate urea (or creatinine) and, if the patient is not anuric, the 24 hour urine urea (or creatinine), if these values are available. If Kt/V or creatinine clearance results were only measured quarterly or each 6-months, enter the FIRST value obtained for each 2-month time period and enter **NP** for any 2-month time period when not performed. If your unit calculates a daily Kt/V or daily creatinine clearance, multiply this result by 7.0 and enter the result in the appropriate space(s).

14. M. Check the method used to calculate the V in the Kt/V measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters - weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank.

14. O. Check Yes or No if the weekly creatinine clearance was normalized for body surface are (i.e., the result is multiplied by the patient's body surface area (BSA) and divided by 1.73m2). If you do not have this information, call the laboratory that provided the weekly Kt/V urea or creatinine clearance value for this information.

15. To respond to questions 15. A - H, record the peritoneal dialysis (PD) prescription in effect at the time the adequacy measures/results you recorded in question 14 were performed. If adequacy measures/results were not performed in each 2-month time period - Nov-Dec 1997, Jan-Feb 1998 & Mar-Apr 1998 - record the first PD prescription found in the medical record for each 2-month time period. Complete all items that are applicable. If the patient was on hemodialysis for an entire 2-month time period, record HEMO in blanks. ONE PD PRESCRIPTION CATEGORY MUST BE COMPLETED FOR EACH 2-MONTH TIME PERIOD, unless the patient was on hemodialysis for the entire 2-month time period.

15. A& B CAPD PRESCRIPTION. Use the CAPD prescription category for CAPD patients only. Enter the inflow volume for a single exchange and number of exchanges per 24 hour period **PRESCRIBED** for CAPD at the time the adequacy measures in question 14 were performed during each 2 month time period: Nov-Dec '97; Jan-Feb '98; & Mar-Apr '98. If different inflow volumes are used, report average inflow volume. If the patient was not on CAPD during the entire 2- month period, enter NP. For CAPD patients who use an automated night time exchange device to provide one additional exchange, check CAPD only.

15. C,D & E. CYCLER NIGHTTIME PRESCRIPTION. Use the CYCLER NIGHTTIME prescription category for Cycler and Tidal patients only. Enter the inflow volume for a single exchange, number of nighttime exchanges per 24 hour period and dwell time for a single exchange (record average time if varied). **PRESCRIBED** for CYCLER NIGHTTIME at the time the adequacy measures in question 14 were performed during each 2 month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any wet day prescriptions (i.e., a last dwell fill that the patient carries after unhooking from the cycler or any daytime dwells) as these exchanges are recorded in the CYCLER DAYTIME prescription below. If different inflow volumes are used, report average inflow volume.

15. F, G & H CYCLER DAYTIME PRESCRIPTION. Use CYCLER DAYTIME prescription category for Cycler and Tidal patients only. Enter the inflow volume, for a single exchange, number of daytime exchanges per 24 hour period and dwell time for a single exchange (record average time if varied) **PRESCRIBED** for CYCLER DAYTIME at the time the adequacy measures in question 14 were performed during each 2 month period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. INCLUDE in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cycler and/or a last dwell fill that the patient carries during the day. (e.g., WET DAY PRESCRIPTION). ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION. If different inflow volumes are used, report average inflow volume.

16. A Enter the MOST RECENT Peritoneal Equilibration Test (PET) results for the four hour Dialysate to Plasma Creatinine ratio (D/P creatinine) test and the date the test was performed. This value should be less than 1 since it is a ratio. The test result and corresponding date performed may be outside the 6-month time frame. If never performed enter **NP**.

17. A. Enter the patient's FIRST hematocrit (HCT) value determined by the laboratory's Coulter Counter or other hematology instrument for EACH 2-month time period: Nov-DEC 1997; Jan-Feb 1998; & Mar-Apr 1998. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.

17. B. Enter the patient's FIRST hemoglobin (HGB) value determined by the labs Coulter Counter or other hematology instrument for EACH 2-month time period: Nov-DEC 1997; Jan-Feb 1998; & Mar-Apr 1998.

17. C. Check the appropriate space to indicate if there was a prescription for EPO in effect during the week the monthly HCT was drawn, EVEN IF the patient did not receive the EPO dose.

17. D. If the answer above is yes, please enter the **PRESCRIBED WEEKLY** EPO dose at the time immediately before the monthly HCT was drawn. If prescribed less frequently than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using a sliding scale for EPO dosing, total all the doses given during the week and enter this value.

17. E Enter the first percent **transferrin saturation** value as a PERCENT obtained for EACH 2-month time period. Please note that this value is usually less than 120%. DO NOT report transferrin or ferritin level for this question. If not performed enter NP.

17. F. Enter the first ferritin value obtained for EACH 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. If not performed enter NP.

17.G. Check the appropriate space (yes or no) to indicate if there was a prescription for Iron in effect at any time during EACH 2-month time period:.

17. H. If the response to 17. G. is yes, please check the appropriate space to indicate the route of iron administration, (intravenously (IV) or by mouth (P.O.)) for each 2-month time period. If the patient received iron by mouth and IV, check both spaces.

18. A. Enter the patient's FIRST serum albumin value recorded for EACH 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998.

18. B. Check the appropriate method used by the lab to determine the serum albumin levels (bromcresol green or bromcresol purple). If you do not know what method the lab used, please call the lab to find out this information; DO NOT LEAVE THIS QUESTION BLANK.

19. Enter the patient's FIRST monthly upright blood pressure (systolic and diastolic) for EACH 2-month time period: Nov-Dec 1997; Jan-Feb 1998; & Mar-Apr 1998. Use clinic/facility records for BP values. If the SBP or the DBP was unobtainable (as opposed to not recorded or not found in the patient's chart), enter UNOB or P for palpated or D for Doppler in the appropriate space.

20. Enter the name and phone number of the person who completed the form & RETURN COMPLETED FORM TO YOUR ESRD NETWORK.

Appendix 5. References

1. Consensus Development Conference Panel. Morbidity and mortality of renal dialysis: An NIH consensus conference statement. Ann Intern Med, 1994; 121:62-70.

2. 1997 ESRD facility survey (HCFA-2744) data, Health Care Financing Administration, Office of Clinical Standards and Quality (report)

3. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. N Engl J Med 1990; 322:707-712.

4. Gagel, BJ. Health Care Quality Improvement Program: A New Approach. Health Care Financing Review 1995; 16(4):15-23.

5. Vladeck, BC. From the HCFA, ESRD Core Indicators Project. JAMA 1995; 273:1896.

6. Health Care Financing Administration. *1994 Core Indicators Project Initial Results. Opportunities to Improve Care for Adult In-Center Hemodialysis Patients.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December, 1994.

7. Health Care Financing Administration. *1995 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December, 1995.

8. Health Care Financing Administration. *Highlights from the 1995 ESRD Core Indicators Project for Peritoneal Dialysis Patients.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December, 1995

9. Health Care Financing Administration. *1996 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, January, 1997.

10. Health Care Financing Administration. *1997 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December, 1997.

11. Dean JA, Burton AH, Coulombier D, Breudel KA, Smith DC, Burton AH, Dicker RC, Sullivan K, Fagan RF, Arner TG. Epi Info, Version 6.04a: a word processing, database, and statistics program for epidemiology on microcomputers. Centers for Disease Control and Prevention, Atlanta, Georgia, U.S.A., 1996.

12. Renal Physicians Association. Clinical practice guideline on adequacy of hemodialysis: Clinical practice guideline, number 1. December, 1993. (pamphlet)

13. NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy. Am J Kidney Dis 1997; 30 (supplement 2).

14. NKF-DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy. Am J Kidney Dis 1997; 30 (supplement 2).

15. NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure. Am J Kidney Dis 1997; 30 (supplement 3).

16. Blagg CR, Liedtke RJ, Batjer JD, Racoosin B, Sawyer TK, Wick MJ, Lawson L, Wilkens K. Serum albumin concentration-related Health Care Financing Administration quality assurance criterion is method-dependent: revision is necessary. Am J Kidney Dis 1993; 21:138-144.

17. Joint National Committee: The Sixth Report of the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 1998; 57: 2413-2446.

18. U.S. Renal Data System, USRDS Annual Data Report, The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 1998, Tables C.5 and C.6.

19. Norusis MJ. SPSS for Windows Advance Statistics Release 6.1. Chicago,IL, USA, 1993.

20. *A Guide For Improving the Quality of Care of Dialysis Patients; the National Anemia Cooperative Project.* US Department of Health and Human Services, Health Care Financing Administration, Baltimore, Maryland, July 1996.

21. Fraser CG, Wilkinson SP, Neville RG, Knox JD, King JC, MacWalter RS. Biologic variation of common hematologic laboratory quantities in the elderly. J Clin Pathology 1989; 92: 465-470.

22. Petronis KR, Carroll CE, Held PJ, Port FK. Effect of race on access to recombinant human erythropoietin in long-term hemodialysis patients. JAMA 1994; 271:1760-1763.

23. Owen WF, Lew NL, Liu Y, Lowrie EG, Lazarus JM. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med 1993; 329:1001-1006.

Appendix 6. List of Publications/Abstracts/Presentations of ESRD Core Indicators Data

Publications

1. Helgerson SD, McClellan WM, Frederick PR, Beaver SK, Frankenfield DL, McMullan M. Improvement in adequacy of delivered dialysis for adult in-center hemodialysis patients in the United States, 1993 to 1995. *Am J Kidney Dis* 29:851-861, 1997

2. Rocco, MV, Flanigan MJ, Beaver S, Frederick P, Gentile DE, McClellan WM, Polder J, Prowant BF, Taylor L, Helgerson SD. Report From the 1995 Core Indicators for Peritoneal Dialysis Study Group.*Am J Kidney Dis* 30:165-173, 1997

3. Flanigan MJ, Rocco MV, Frankenfield DL, Bailie G, Frederick PR, Prowant, BF, Taylor L. 1996 Peritoneal Dialysis-Core Indicators Report. *Am J Kidney Dis* 32:1-9, 1998

4. Frankenfield DL, McClellan WM, Helgerson SD, Lowrie EG, Rocco MV, Owen WF. Relationship between urea reduction ratio, demographic characteristics, and body weight for patients in the 1996 national ESRD Core Indicators Project. *Am J Kidney Dis* [in press]

5. Rocco MV, Flanigan MJ, Prowant B, Frederick P, Frankenfield DL. Cycler adequacy and prescription data in a national cohort sample: The 1997 ESRD Core Indicators Report. *Kidney Int* [in press]

6. Frankenfield DL, Prowant BF, Flanigan MJ, Frederick PR, Bailie GR, Helgerson SD, Rocco MV. Trends in clinical indicators of care for adult peritoneal dialysis patients in the U.S., 1995-1997. *Kidney Int* [in press]

7. Bailie GR, Frankenfield DL, Prowant BF, McClellan NM, Rocco MV. Erythropoietin use and hematocrit control in peritoneal dialysis patients. Report from the 1997 HCFA End-stage Renal Disease Core Indicators Project.*Am J Kidney Dis* [in press]

Abstracts

1. Frankenfield DL, Frederick PR. Epoetin alfa (EPO) Dosing Patterns for In-Center Hemodialysis Patients - a National and Regional Snapshot. *International Pharmaceutical Abstracts* 33(21):2283, 1996.

2. Rocco M, Flanigan M, Frederick P, Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Serum Albumin and Dialysis Adequacy. *J Am Soc Nephrol* 7 (September): 1067A, 1996.

3. Flanigan M, Rocco M, Frederick P. Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. *J Am Soc Nephrol* 7 (September):990A, 1996.

4. Prowant BF, Taylor L, Frederick PR. Health Care Financing Administration (HCFA) 1995 Core Indicators for Peritoneal Dialysis. *ANNA Journal* 24:196, 1997.

5. Bailie G, Frankenfield D, Frederick P, Rocco M, Prowant B, Flanigan M. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. *J Am Soc Nephrol* 8 (September):215A, 1997.

6. Rocco M, Flanigan M, Prowant B, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): CAPD Prescription and Adequacy Data. *J Am Soc Nephrol* 8 (September):289A, 1997.

7. Rocco M, Flanigan M, Prowant B, Bailie G, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Cycler Prescription and Adequacy Data. *J Am Soc Nephrol* 8 (September):290A, 1997.

8. Frankenfield DL, Frederick PR. Comparison of Epoetin Alfa (EPO) Dosing Patterns for In-Center Hemodialysis and Peritoneal Dialysis Patients - the 1996 End Stage Renal Disease (ESRD) Core Indicators Project. *International Pharmaceutical Abstracts* 34(21):2212, 1997.

9. Flanigan MJ, Bailie G, Frankenfield D, Frederick P, Prowant B, Rocco M for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Albumin (Alb) and Nitrogen Appearance (nPCR) Data. *J Am Soc Nephrol* 8:192A, 1997.

10. Bailie GR, Frankenfield DL, Frederick P, Prowant BR, McClellan W, Rocco MV, Flanigan M. Epo Use and Hct Control in Peritoneal Dialysis (PD) patients,: Report from the 1997 ESRD Core Indicators Project (CIP). *J Am Soc Nephrol* 9 (September): 139A, 1998.

11. Wish JB, Frankenfield DL, Frederick PR, Owen WF, Johnson,CA, Rocco MV. Iron Management and Hematocrit Control in Hemodialysis Patients. Report from the 1997 HCFA Core Indicators Project. *J Am Soc Nephrol* 9 (September):230A, 1998.

12. Flanigan M, Rocco MV, Frankenfield D, Bailie G, Frederick P, Prowant B, Taylor L the PD-CIS Workgroup. 1997 ESRD Core Indicators Study for Peritoneal Dialysis (PD-CIS). Nutritional Indicators. *J Am Soc Nephrol* 9 (September):233A, 1998.

13. Rocco M, Frankenfield D, Frederick P, Flanigan,M, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Trends in Clinical Indicators of Care for Adult Peritoneal Dialysis Patients in the U.S. from 1995 to 1997, Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 9 (September):301A, 1998.

14. Rocco M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Cycler Adequacy and Prescription Data in a National Cohort Sample: The 1997 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 9 (September):301A, 1998.

15. Frankenfield DL, Johnson CA, Bailie GR. Management of Anemia in End Stage Renal Disease (ESRD) Patients in the U.S.: Results from the 1997 ESRD Core Indicators Project. *International Pharmaceutical Abstracts* 35(21):2292, 1998.

Presentations

1. Frankenfield DL, Frederick PR. Epoetin alfa (EPO) Dosing Patterns for In-Center Hemodialysis Patients - a National and Regional Snapshot. Poster presentation at the American Society of Healthcare Pharmacists Midyear Clinical Meeting, New Orleans, LA. 1996.

2. Rocco M, Flanigan M, Frederick P, Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Serum Albumin and Dialysis Adequacy. Poster Presentation at the 29th Annual Meeting of the American Society of Nephrology, New Orleans, LA. 1996.

3. Flanigan M, Rocco M, Frederick P. Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. Poster Presentation at the 29th Annual Meeting of the American Society of Nephrology, New Orleans, LA. 1996.

4. Bailie G, Frankenfield D, Frederick P, Rocco M, Prowant B, Flanigan M. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. Oral presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.

5. Rocco M, Flanigan M, Prowant B, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): CAPD Prescription and Adequacy Data. Poster presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.

6. Rocco M, Flanigan M, Prowant B, Bailie G, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Cycler Prescription and Adequacy Data. Poster presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.

7. Frankenfield DL, Frederick PR. Comparison of Epoetin Alfa (EPO) Dosing Patterns for In-Center Hemodialysis and Peritoneal Dialysis Patients - the 1996 End Stage Renal Disease (ESRD) Core Indicators Project. Poster presentation at the American Society of Healthcare Pharmacists Midyear Clinical Meeting, Atlanta, GA. 1997.

8. Frederick PR, Frankenfield DL. ESRD Core Indicators Project - A Health Care Quality Improvement Program Project Focused on Improving Care for Hemodialysis Patients. Poster presentation at the Ninth Annual National Forum on Quality Improvement in Health Care, Orlando, FL. 1997.

9. Bailie GR, Frankenfield DL, Frederick P, Prowant BR, McClellan W, Rocco MV, Flanigan M. Epo Use and Hct Control in Peritoneal Dialysis (PD) patients: Report from the 1997 ESRD Core Indicators Project (CIP). Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.

10. Wish JB, Frankenfield DL, Frederick PR, Owen WF, Johnson, CA, Rocco MV. Iron Management and Hematocrit Control in Hemodialysis Patients. Report from the 1997 HCFA Core Indicators Project.Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.

11. Flanigan M, Rocco MV, Frankenfield D, Bailie G, Frederick P, Prowant B, Taylor L the PD-CIS Workgroup. 1997 ESRD Core Indicators Study for Peritoneal Dialysis (PD-CIS). Nutritional Indicators. Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.

12. Rocco M, Frankenfield D, Frederick P, Flanigan,M, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Trends in Clinical Indicators of Care for Adult Peritoneal Dialysis Patients in the U.S. from 1995 to 1997, Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Oral and Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998

13. Rocco M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Cycler Adequacy and Prescription Data in a National Cohort Sample: The 1997 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.

14. Frankenfield DL, Johnson CA, Bailie GR. Management of Anemia in End Stage Renal Disease (ESRD) Patients in the U.S.: Results from the 1997 ESRD Core Indicators Project. Poster presentation at the American Society of Healthcare Pharmacists Midyear Clinical Meeting, Las Vegas, NV. 1998 .